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Life Study Pilot

Technical report and key findings on Pilot development and fieldwork

LIFE STUDY | Understanding lives – now and for the future

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Date: 11 March 2014
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1 Summary

1.1 Introduction

- In this report, NatCen provides a summary of the work commissioned by UCL in February 2013 to provide fieldwork expertise to the Life Study during the pilot phase of the project.
- It is important to note that this work is based on the design of the Study as outlined in the December 2012 tender which may not reflect the current design proposed for Life Study.
- As well as giving details of the work undertaken during this pilot phase, the report aims to provide information which, where relevant, will guide the design and conduct of the operational phase of the Study.

1.2 Context

- Life Study is a longitudinal study that will track the growth, development, health, well-being and social circumstances of approximately 100,000 UK babies and their families. The Study comprises two key components, the Pregnancy Sample and the Birth Sample. The Pregnancy Sample will comprise around 90,000 pregnant women identified through selected maternity units. Mothers will be invited to attend a Life Study assessment centre on three occasions: once when pregnant and twice within the first year of their baby's life.

  This report presents the findings of the pilot study of the pregnancy component. The pilot objectives, as set out in the ITT, were to validate, test and operationalise the Study, the scientific protocol and instrumentation. The report also acts as a technical report of the fieldwork element of the pilot
- The purpose of any pilot is to learn lessons for the main stage: we expect to find things that need to be improved. This will be particularly true of an enterprise as ambitious and innovative as Life Study. We draw out the key findings with implications for the main stage in this summary.
- The pilot took place over 32 days (28 October – 28 November 2013 inclusive) in an NHS Clinic. As the principal investigator, the UCL team was primarily responsible for preparing the research ethics and governance application and participant materials, specifying the pilot content, providing the pilot venue and recruitment of participants. The focus of the work undertaken by NatCen Social Research was to test and validate the protocol and inform the process for operationalising the specification. This required data collection and providing the Life Study team with on-going progress reports highlighting issues and risks arising.

1.3 Recruitment and response

- A target of 50 pregnant mothers and 25 in each of the other groups (partners, mothers of 6 month olds and mothers of 12 month olds) was agreed, totalling 125. During the course of the pilot, 41 interviews took place against the target of 125 interviews. 26 interviews were achieved with pregnant women, which were the

priority group; but the shortfall was particularly pronounced among partners of pregnant women, and women with young babies, where only 4-6 interviews were achieved with the three relevant groups. (See 9.1)

Recruitment of the main stage sample will be different to the pilot – via maternity units rather than volunteer samples recruited through posters, word of mouth and website notices. However, the experience of participants is relevant to securing good response rates, and this is discussed in Section 19.5. Furthermore, the low numbers of partners is a cause for concern because of the particular problems around encouraging partner participation (See below). Particular thought will need to be given to engaging partners and within Life Study the "Father sub-group" is developing a strategy to address some of these issues.

Although recruitment of mothers with young babies was challenging in the pilot, babies will not be recruited after birth in the main stage. However, it is still important to consider the issues that recruiting this group raised in order to ensure that any potential for drop-out between the visits can be kept to a minimum.

1.4 Recruitment and response

- Participants were advised that the visit would take up to three hours. This was to accommodate the 90 minutes of planned activities and an additional buffer to allow time for extra questions. In practice the mean visit across all four groups took 2 hours 46 minutes. However, visits took much longer with mothers of young babies: 3 hours 25 minutes for those with the youngest babies and 4 hours 20 minutes for those with older babies. The maximum time was 5 hours. It is important to note here that visit time refers to the time the participant arrived in clinic to the time they left the unit. In addition, as discussed further in section 10.2.4, more questionnaire material was deliberately included for the pilot than is planned for the main stage.

1.5 The participant experience

- To assess the participant experience, 24 qualitative telephone interviews were conducted with participants as a follow up to their visit, using an unstructured topic guide. Generally, their experience was felt to be worthwhile and interesting, but too long. Participants reported that they would like to have had more detailed information about what to expect to allow them to prepare, particularly given the length of sessions.
- Participants/babies particularly enjoyed the eye-tracking and vision assessments. However in the longer visits babies could become too tired to engage with the tasks.

1.6 Logistics

- **Venue**. Due to the need to identify a location which was able to provide weekday access, there was a delay in confirming the venue. This delay resulted in a number of operational challenges. It introduced a late requirement for research passports which resulted in operational delays; introduced timing and functionality restrictions in the venue (e.g. the need to set up and pack away each day; and lack of fully appropriate connectivity – WiFi and Internet); and was not considered a

wholly appropriate space for children. This could be overcome for the main stage with advanced planning of the venue.

- **Participant flow**. A fixed schedule resulted in bottlenecks and the ability to vary the order of stations appeared to improve flows. However, more work is needed to evaluate how the flows will work in practice given changes to the design and the venue set up for the mainstage.

1.7 Development and Planning

- **Questionnaire development.** The final questionnaire length averaged 72 mins against the original target of 48 mins and a revised target of 60 mins. The content of the questionnaire tested in the pilot was achieved through consultation with scientific experts and was longer than will be used in the main stage. It is understood that final decisions about content will be made through consensus between the scientific stakeholders taking into consideration results from the pilot. Thus the length of the questionnaire will be reduced for the main stage of the Study.
- **Instrument development**. The length of questionnaire clearly had implications for the instrument development and testing approaches. Changes to the questionnaire specification in terms of length and also between mode (CAPI/CASI), sweep and participant type after programming had begun resulted in the need for extra resource to meet the overall timetable. These can be addressed for the main stage if the content is finalised prior to programming.

1.8 Achievement of pilot objectives

- The original pilot objectives were to work with the Life Study team to validate, test and operationalise the scientific protocol and the instrumentation. The work undertaken has provided a basis from which to do this, which will be taken forward in the next stage of the Study. However, the low level of recruitment and issues with the venue resulted in difficulties specific to the pilot, which did not allow for full testing of the protocol.

2 Introduction

The Life Study is a longitudinal study which will track the growth, development, health, well-being and social circumstances of approximately 100,000 UK babies and their families. The Study comprises two key components, the Pregnancy Sample and the Birth Sample.

The Pregnancy Sample will comprise around 90,000 pregnant women identified through selected maternity units. Mothers will be invited to attend a Life Study assessment centre on three occasions:

- at 28-30 weeks of pregnancy;
- when their child is approximately 6 months old and
- when their child is approximately 12 months old.

At the 28-30 week visit, mothers will be asked to identify their partner who will also be invited to attend the Life Study assessment centre.

At the end of February NatCen was awarded the contract to undertake the pilot phase of the Life Study Pregnancy Sample.

3 Aims of the (Pregnancy Sample) Pilot contract

The aims of the pilot as set out in the ITT were:

- To validate, test and operationalise the Study, the scientific protocol and instrumentation (Section 5 onwards).
- To develop the Birth Sample sampling specification in collaboration with the Life Study team and other stakeholders (Section 4).

4 National Probability (Birth) Sample

As part of the pilot contract NatCen was required to work with the Life Study team and other stakeholders to develop the birth sampling specification. Three meetings between 10 April and 16 September took place at ICH resulting in a paper submitted to the Life Study team at the end of September 2013.

5 Project Management

5.1 Timeline

From award of contract (March 2013), the aim was to conduct the pilot data collection, provide clean data and a full technical report by the end of December 2013. Data collection was to take place in the antenatal clinic facilities within University College London Hospital (UCLH) which would only have been available out of hours over a number of weekends during 2013.

Given that it would not be possible, within the timescale for the pilot, to mirror the longitudinal nature of the Study, four participant sample groups were identified: mum-to-be who were 28 weeks pregnant (M28), partners of pregnant mum-to-be (P28), mums with a 6 month old (M6) and mums with a 12 month old (M12).

5.1.1 Participant types

Table 5.1 Participant types

Description	Label
Pregnant women (after 20 week scan but before birth)	M28
Partners of women fulfilling the M28 criteria	P28
Mothers with a baby 4 to 8 months old	M6
Mothers with a baby 10 -14 months old	M12

A top-level timeline was circulated in mid April and reviewed and modified periodically. The timeline identified critical delivery dates from a fieldwork perspective. These included:

- Receipt of questionnaire modules in a state ready for programming
- Sign-off on finalised questionnaire content
- Receipt of measurement equipment (excluding consumables)
- Confirmation of REC approval for pilot (which would allow recruitment of participants to begin)
- Receipt of finalised measurement content to allow development of the SOPs and related training materials
- Sign-off on recruitment and sample file
- Confirmation of pilot venue including operational hours and arrangements

There were many unanticipated difficulties which resulted in delays to elements of this timetable causing some operational problems and requiring 'work-arounds'.

5.2 Scope of the Pilot

The content of the Pilot included:

- CAPI (Computer Assisted Personal Interviewing) interview i.e. questions administered face-to-face by an experienced interviewer
- CASI interview (Computer Assisted Self-administered Interview)
- Pre-visit questionnaires to be completed by participants prior to their visit
- Adult and infant Anthropometry measurements including accelerometry
- Adult and infant Vision measurements
- Child Development Observations
- Collection of bio-samples
- Post-visit question to be completed and returned

5.3 Budget

The budget agreed at the start of the contract was based on having four questionnaires with around 45 minutes of question time, a total clinic visit time of 90 minutes per participant and pilot data collection during nine 7-hour weekend days with between 6 and 8 staff in total (6 for M28, P28 and M6 participants, 8 for M12 participants).

Revised costs were submitted to reflect the final content and structure of the pilot i.e. eight 8-hour weekend days using 9 staff per shift, 24 5-hour weekday shifts with either 4 (Fri) or 7 (Mon-Thu) staff. Due to the increased number of shifts the number of interviewers to be trained increased from 11 to 21. Programming costs were also increased as the estimated question time increased and the IT support costs were also revised to reflect the increased number of pilot days.

Additional costs incurred also included the loan of the accelerometers and cost of interviewer trips to Occupational Health appointments required as part of the Research Passport process.

5.4 Communication

Throughout the contract NatCen and the Life Study team at ICH kept in regular contact via emails, telephone calls and face to face meetings. In addition NatCen submitted a written monthly progress report for the Life Study Project Board. The format of the reports covered progress against payment milestones, summary of key areas of work, progress against the project plan, current issues log and a risk register.

During the data collection phase, at the end of each shift the lead NatCen Researcher and Life Study team member would have a brief catch-up to highlight any issues arising. This was followed up by an email from NatCen the following day listing progress to date, outcome and timing of the previous day's interviewing and all issues (current and outstanding).

6 Summary of Pilot response – counts and timings

In total the pilot consisted of 41 participants whose total visit time including any breaks required for lunch, snacks or nappy changes, ranged from just under 2 hours to just over 5 hours.

Table 6.1 Dashboard data – counts

	M28	P28	M6	M12	ALL
RESPONDENT COUNT	26	6	4	5	41

Table 6.2 Total visit time (from Participant Summary Sheets)

	M28	P28	M6	M12
TOTAL VISIT TIME (mean)	2hr 28min	2hr 21min	3hr 27min	4hr 24min
TOTAL VISIT TIME (min)	1hr 50 min	1hr 55min	1hr 48min	4hr 00min
TOTAL VISIT TIME (max)	3hr 00min	2hr 40min	4hr 50min	5hr 05min

Further breakdown of counts and timings are covered in Section 9.2.

7 Ethics application (REC)

Ethics approval had to be sought from the NHS Research Ethics Committee (REC) London – City & East. The Life Study team at ICH were responsible for all aspects of the ethics approval. An initial ethics approval for the study was in place at the outset of the contract, but REC approval for the Pilot data collection was required and the initial timeline was to submit the papers in June with the intention of getting approval in July.

NatCen reviewed the Pilot materials prior to its submission of these to the REC as a substantive amendment by the Life Study team. Where discrepancies were identified by NatCen or UCL the materials were updated. Documents were first submitted to the REC on 14th June 2013 and, after revisions, the REC approved the Pilot on 10th September 2013.

Having REC approval in place was a prerequisite for the start of recruitment of pilot participants. As this was not in place until 10th September 2013, the Telephone Unit briefing and start date had to be postponed.

8 Cognitive Testing

As part of the pilot development phase, cognitive interviews were carried out between 14th May and 14th June 2013, which tested proposed new or significantly modified questions that are being considered for inclusion in the early rounds of data collection

on the Life Study. Each interview lasted approximately one hour and was audio recorded with the respondent's consent. Respondents were given a £20 high street voucher as a token of our appreciation for taking part in the interview.

The cognitive testing protocols were developed in consultation with the Life Study team at ICH and were reviewed by NatCen's internal ethics committee.

The testing explored:

- Comprehension of the question task (i.e. do respondents understand what they are being asked to do/ asked for);
- comprehension of key terms within the questions;
- ability of respondents to recall the information being sought; and
- to ascertain whether respondents felt willing and able to answer 'honestly'.

The questions tested were:

  - Environmental questions on: cooking; the home; exposure to chlorinated water;
  - Mother's and partner's health;
  - Baby's health;
  - Childcare;
  - Mother & partners reading and praying;
  - Language(s) spoken at home to the baby;
  - Drinking alcohol during pregnancy and partner's alcohol drinking;
  - Fluid Intelligence measurement; and
  - Knowledge of how babies learn.

Some aspects of the proposed advance materials that would be sent to interested pregnant women and their partners, explaining about the Life Study and inviting them to take part were also tested.

The full report was submitted as per the agreed timetable on 10 July 2013.

9 Response

9.1 Pilot sample – target and achieved

Table 9.1 Pilot sample – target vs. achieved

Description	Label	Target	Interviewed
Pregnant women (after 20 week scan but before birth)	M28	50	26
Partners of women fulfilling the M28 criteria	P28	25-50	6
Mothers with a baby 4 to 8 months old	M6	25	4
Mothers with a baby 10 -14 months old	M12	25	5

9.2 Detailed counts and timings

Detailed counts and timings were captured in a daily 'dashboard' report which was made available to the Life Study team via the secure ftp server. Timings for each station were recorded from the time of entry to the station to the time of exit, and so include additional time taken due to unexpected delays that were not part of the scientific protocol, such as reconfiguring the wifi/PC or seeking additional interviewer assistance with equipment.

Table 9.2 Dashboard data – counts

	M28	P28	M6	M12	ALL
RESPONDENT COUNT	26	6	4	5	41
No. of travel payments envelopes given*	26	6	8	5	45
STATION OVERVIEW (COUNTS)					
Pre-complete – completed prior to clinic visit	n/a	n/a	3	5	8
Pre-complete – completed in clinic	n/a	n/a	1	0	1
Consent signed	26	6	4	5	41
CAPI station visited	26	6	4	5	41
CASI 1 station visited	26	6	3	5	40
CASI 2 station visited	24	5	3	5	37
Child development observations station visited	n/a	n/a	3	5	8
Child vision station visited	n/a	n/a	n/a	4	4
Adult vision station visited	25	6	n/a	n/a	31
Child eye tracking station visited	n/a	n/a	3	5	8
Adult anthropometry station visited	26	6	n/a	5	37
Baby anthropometry station visited	n/a	n/a	4	5	9
Measurements (COUNTS) exc refusal/not measured					
Infant urine collected (sample discarded on site)	n/a	n/a	2	4	6
Infant saliva collected	n/a	n/a	3	3	6
Infant eye tracking completed	n/a	n/a	3	5	8
Child observations (COUNTS) exc refusal/not measured					
Mother still face	n/a	n/a	3	n/a	3
Car seat restraint	n/a	n/a	3	n/a	3
Highchair restraint	n/a	n/a	n/a	5	5
Joint attention task	n/a	n/a	n/a	5	5
Adult anthropometry (COUNTS) exc refusal/not measured					
Adult BIA	22	6	n/a	5	33
Adult weight	26	6	n/a	5	37
Adult height	26	6	n/a	5	37
Adult sitting height	26	n/a	n/a	n/a	26
Adult waist	n/a	6	n/a	5	11
Adult skinfolds – triceps	25	6	n/a	5	36
Adult skinfolds – subscapula	21	6	n/a	5	32

Table 9.2 Dashboard data – counts					
Adult MUAC	26	6	n/a	5	37
Baby anthropometry (COUNTS) exc refusal/not measured					
Infant weight	n/a	n/a	4	5	9
Infant length	n/a	n/a	4	5	9
Infant skinfolds (triceps and subscapular)	n/a	n/a	4	5	9
Infant head circumference	n/a	n/a	4	4	8
Infant MUAC	n/a	n/a	4	5	9

* Those attending the clinic were provided with £11 to cover travel expenses. If they attended with another adult, they were able to claim two travel payments.

Table 9.3 Dashboard data – timings (minutes) for CAI elements					
	M28	**P28**	**M6**	**M12**	**ALL**
TOTAL DATA COLLECTION TIME (mean)	148	141	205	260	166
TOTAL DATA COLLECTION TIME (min)	108	114	108	239	108
TOTAL DATA COLLECTION TIME (max)	176	160	283	297	297
COUNT	26	6	4	5	41
MODULE TIMING (mean)					
Booking in	2	1	2*	2	3
CAPI and consent	24	21	30	30	25
CASI 1	20	27	24	17	21
CASI 2	28	24	26	18	26
Child development observations	n/a	n/a	28	17	21
Child vision	n/a	n/a		16	16
Adult vision	16	17	n/a	n/a	16
Child eye tracking	n/a	n/a	15	16**	16
Baby saliva	n/a	n/a	7	7	7
Adult anthropometry	25	20	n/a	23	24
Baby anthropometry	n/a	n/a	22	23	22
MODULE TIMING (min)					
Booking in	1	1	2	1	1
CAPI and consent	16	13	19	22	13
CASI 1	9	16	15	12	9
CASI 2	19	12	18	12	12
Child development observations	n/a	n/a	21	11	11
Child vision	n/a	n/a		10	10
Adult vision	6	7	n/a	n/a	6
Child eye tracking	n/a	n/a	12	13	12
Baby saliva	n/a	n/a	5	5	5

Table 9.3 Dashboard data – timings (minutes) for CAI elements					
Adult anthropometry	16	18	n/a	14	14
Baby anthropometry	n/a	n/a	20	15	15
MODULE TIMING (max)					
Booking in	6	2	3*	2	6
CAPI and consent	41	26	38	42	42
CASI 1	28	44	37	20	44
CASI 2	41	29	39	28	41
Child development observations	n/a	n/a	34	24	34
Child vision	n/a	n/a		25	25
Adult vision	34	32	n/a	n/a	34
Child eye tracking	n/a	n/a	19	22**	22
Baby saliva	n/a	n/a	9	8	9
Adult anthropometry	38	25	n/a	40	40
Baby anthropometry	n/a	n/a	23	30	30

*One booking in time was recorded as 39 minutes. This outlier has been removed as it will be due to recording error rather than being a real time.
** One M12 child eye tracking was timed at 51 minutes. This outlier has been removed from the calculations as it will be recording error rather than a real time.

10 Questionnaire development

10.1 Serial number

Each participant was allocated a unique serial number to enable data linkage throughout the survey process. NatCen proposed a serial number format that could, if required, be used or adapted for use in the main stage. The format is a six-digit number as follows:

Location
1=UCLH. ('1' for all respondents in the pilot)
2+= main stage Innovation Centres and Assessment Centres

Visit type/Sweep
1=28 week visit i.e. 1 for both M28 and P28 participants
2=6 month visit
3=12 month visit
4+ = subsequent data collection sweeps

Family group
00-99. This number is used to link mother, partner and baby/ies within the same family group.

Respondent type
01=mother
02=partner
03-99=baby

As the pilot was not required to cater for multiple births it was agreed that all data would be collected within the mother's serial number i.e. baby observations saved under the relevant M6 or M12 serial number.

10.2 Development of questionnaire content

10.2.1 Initial documentation provided to NatCen

Following the initiation meeting, NatCen received the questionnaire content documentation for the Pilot questionnaire. The documentation consisted of:

- A 'Life Study Scientific Protocol' spreadsheet
- 21 individual Word or pdf files containing questionnaire content, one document per module (i.e. topic)

The protocol spreadsheet provided data such as estimated timings for each question or sets of questions (based on prior use in previous cohorts or expert consensus), module, source of question, mode and sweep. It also contained a brief description of measures.

The spreadsheet also contained material and measures that weren't intended to be included in the Pilot, for example detailed information to be obtained from maternity notes, markers of Vitamin D status from serum samples and testing sensorineural hearing loss via routine newborn hearing screening.

The modular Word documents contained questions to be asked, source of question and who questions should be asked of. It did not contain mode so the protocol spreadsheet was required for cross-reference.

23 module specifications were provided to NatCen. These included the CAI questions and the questions to be included in the pre-complete and post-visit questionnaires.

Modules are listed below.

- Initial CAPI questions
- Demographics
- Identity
- Parental and family health
- Parental and mental health
- Parental behaviour and lifestyle
- Parental education
- Parental employment
- Financial situation
- Pregnancy and birth
- Child health
- Child development

- Child sleeping and crying
- Diet and nutrition
- Infections and immunity
- Childcare
- Parenting
- Family relationships
- Social networks and support
- Housing
- Neighbourhood
- Environment
- Vision

10.2.2 Review of questionnaire wording

When NatCen first received the pilot questions from UCL it was necessary to review these questions and create a useable questionnaire specification for programming. At the time a number of concerns were raised about the questionnaire material. Examples included:

- Potentially sensitive questions e.g. asking pregnant women about abortions and children who have died.
- Loss of contextual framework e.g. picking one or two questions from a series of questions used on other surveys.
- Potentially confusing question wording e.g. questions with ambiguous or overlapping response categories

The Life Study team were keen to keep the content as agreed and signed off by the Life Study Scientific Steering Committee as a result of the protocol consultation undertaken in summer 2012. The Life Study team had undertaken a process of consultation with experts prior to commissioning NatCen, and were keen to formally test the content as supplied and to make changes based on evidence from the Pilot. Prior to data collection NatCen highlighted to the Life Study team that they were still concerned that participants may feel uncomfortable and/or confused by some of the questions that existed in the pilot questionnaires.

10.2.3 Module template specifications

NatCen reviewed the proposed questionnaire content in more detail and identified further detail that was required to create a specification that could be used for programming as a CAI instrument. There was some confusion as to where the responsibility for creating the specification lay. The tender had said that a questionnaire specification existed, but UCL and NatCen had a different understanding of what this meant.

Elements of the content that required further clarity for programming included:

- The protocol spreadsheet and Word documents did not always correspond about who should be asked which questions and in which mode. For example, questions

requiring participants to look at show cards were specified as being asked in the pre-complete questionnaire according to the protocol spreadsheet.

- Filtering on whether the participant already has children; there was lack of clarity on age of child, whether it included stepchildren, whether they were resident or non-resident.
- Filtering on whether the M28 has other children who will be siblings to the unborn baby; there was no clear definition of sibling and more clarity about why the question was being asked (e.g. whether it was examining biological or social impacts on health) was required to ensure that the definition used was appropriate.
- Textfills for year/age were specified but there was no indication of the relevant reference time period that the analysts would be interested in
- Whether loops were required or whether the intention was to ask a question once only (e.g. use of regular medicine)
- Filtering conditions based on variables that did not appear in the Word documents
- Ambiguous filtering conditions based on text descriptions rather than variable names
- Missing filtering, which meant respondents would be asked questions which might not apply to their situation. E.g. questions about hospital/unit where gave birth were not filtered from whether was a home birth or in hospital.
- The documentation contained some feed forward items (i.e. filtering based on previous sweeps), which would be used for the longitudinal study. As pilot participants would only be attending the clinic once, feed forward would not be possible and these filters were not appropriate for use in the Pilot context.
- The Word documents sometimes contained comments and queries about the content but it was unclear whether the comments should be acted on for the Pilot.

Therefore, a detailed review process was required and NatCen researchers sought clarification to resolve various issues before the content was in a sufficiently-specified state to allow programming to begin.

To help this process, NatCen proposed a structured format where each question is accompanied by the critical components that are needed for programming including question wording, response categories, filtering conditions, textfills etc. This was dual purpose, serving as the specification for programming as well as the documentation of the questionnaire content. A further benefit of this approach allows the holders of the master specification (in this case ICH) to take control of the material to be used and manage the content with a longitudinal framework in mind.

As the timetable did not include this initial process and resources were not available at UCL, NatCen created the first version of each module specification, transferring the provided content as a basis and noting queries where necessary.

Subsequent versions of the template module specifications were updated by UCL pre- and post-cuts (see section 10.2.4). UCL held the master specification documents to ensure that the content remained in their control and was programmed as specified.

10.2.4 Length of questionnaire

The budget agreed at the start of the contract was based on having four questionnaires with around 45 minutes of question time, and a total 'test' time of 90 minutes, which was the aim for the main stage at that time. It is usual for a pilot study to contain slightly more material than the main stage to allow final refinements to be made before the main stage. UCL therefore looked to pilot approximately 25% more material than the initial planned interview length at each visit.

The table below shows the estimated CAPI and CASI timings based on the initial questionnaire content with UCL's suggested times for the main stage in brackets

Table 10.1 Initial content: CAPI, CASI timing estimates (initially proposed timings in brackets)

	M28	P28	M6	M12
CAPI	35 mins (15)	23 mins (15)	21 mins (10)	23 mins (10)
CASI	43 mins (40)	35 mins (40)	43 mins (30)	50 mins (30)

During initial discussions it was agreed that there was too much material to include at the pilot and that UCL should further reduce the content to be closer to the suggested times shown in brackets. As UCL were hoping to pilot approximately 25% more material than the initial estimated interview length at each visit the aim was to cut around 12 minutes from the pregnancy visit, 15 minutes from the 6 month and 31 minutes from the 12 month visit.

NatCen specified that reduced questionnaire content (including the partner proxy) would be needed by the end of the April in order to get the material programmed and tested ready for the Pilot launch. In mid April Life Study requested that NatCen should programme all of the proposed questionnaire data for the Pilot and indicated that any cuts would be made post-pilot. However, this decision was later revised by UCL who advised NatCen that the content would need to be cut prior to data collection at the Pilot clinic.

Cuts to the Pilot questionnaire content had to be agreed and approved by the Life Study Scientific Steering Committee (SSC) and discussion about these proposed cuts took place at the July SSC meeting. NatCen received final questionnaire (CAPI and CASI) content specifications and module order on 22 July.

Revised estimates of timings were provided to NatCen by UCL based on SSC review of the questionnaire content. See table below (note this covers questionnaire data collection only, no measurements included).

Table 10.2 Revised content (post-cuts) timing estimates CAPI, CASI (initially proposed timings in brackets)

	M28	P28	M6	M12
CAPI	21 mins (15)	15 mins (15)	18 mins (10)	17 mins (10)
CASI	51 mins (40)	46 mins (40)	30 mins (30)	42 mins (30)

In order to accommodate this change in development timetable, NatCen increased the number of programmers working on the development of the CAI questionnaire during May and June. While NatCen waited for final questionnaire content to be provided, programmers worked on developing the CAI framework (questionnaire and measurement blocks). This allowed for questionnaire changes to be actioned more quickly within the overall timetable when final questionnaire content was provided to NatCen in July.

10.2.5 Variable names

Variable names were only rarely specified in the proposed questionnaire content documents provided by UCL. Where these were specified, NatCen used these names. During the production of the module template specifications NatCen created variable names for each data collection item.

In early June, as a result of some inconsistencies in variable naming, it became clear that a review of the variable names being used was required with the aim of producing a more consistent naming convention that could be used throughout all sweeps of Life Study. NatCen produced a written document containing the options for UCL to consider. After further review, UCL produced a variable names specification.

As most of the draft module specifications had already been submitted to UCL, and a decision had been made that renaming could not be done post data collection, a phased approach to replacing variable names was adopted:

- For module template specifications yet to be finalised, NatCen ensured that variable names conformed to the specification.
- Where module template specifications had been submitted, UCL produced an Excel listing of all current variable names (split by module). Where NatCen identified a variable name as contravening the specification, a new variable name was proposed and noted in the Excel listing.
- The Excel listings were returned to UCL to update the module template specifications.
- Four of the (post-cut) module template specifications were not updated with the revised variable names. UCL requested that NatCen implement the revised variable names using the Excel listings for these four modules.

Initiating a review of the variable names during the questionnaire programming phase was an additional complication to the CAI development. On provision of the final module specifications, programmers were required to review and revise the code, which contained complex filtering within and across the 23 questionnaire modules.

The timing and prioritisation of the variable name review had further implications for testing of CAI content. Additional time was required to ensure that variable names were correct as per the module specifications. Programmers were required to amend variable names in the code when they were concurrently developing complex clinic systems and integration of devices.

10.2.6 Development of measurement administrative data collection

The administrative CAI content that enabled data collection at each of the measurement stations (i.e. content that was not included in the template module specifications) was developed by the NatCen research team following sign-off of the

SOPs. Where possible, protocol was incorporated into the CAI as an interviewer instruction to act as an additional reminder for interviewers.

10.3 Overall structure of Pilot data collection menu system

10.3.1 Summary

Once final questionnaire content was received, development began on the structure of the menu system for navigating through the various components of the Pilot data collection.

During the early stages of programming consideration of how best to structure the CAI with regards to sweep and participant type took place (i.e. whether the interview was with an M28/P28, M6 or M12). Due to the level of duplication of questionnaire content across sweeps and the unknown level of cuts and final structure, the decision was made to create one Pilot program and use sweep as a top level filter rather than to develop three distinct programmes for pregnancy, 6-month and 12-month.

10.3.2 Overview of structure

The menu system was set up to mirror the clinic stations/rooms for data collection, with a separate 'block' for each station. Interviewers selected the relevant station from the menu, which listed all the possible stations. Following the verification of the participant, the interviewer could then proceed with the measure. The structure of the menu system is outlined below.

- **Reception (In):** short reception questionnaire to 'book in' and capture key information from participants on arrival for their appointment.
- **CAPI:** interviewer-administered face-to-face interview. Questions covered background information such as demographics, financial status and fertility history.
- **Consent form:** program to interface with the consent tablets used to administer consent forms, collect digitised signatures and print hard copies for participants to take away.
- **CASI (Part 1):** first part of self-completion interview using touch screen computer.
- **CASI (Part 2):** second part of self-completion interview using touch screen computer.
- **Vision:** administrative questions and interviewer protocol instructions, plusoptiX interface and post-assessment vision questions.
- **Anthropometry:** adult and baby anthropometry content, including protocol and consent checking instructions for interviewers, fields to record measurements where appropriate and administrative quality control data e.g. reliability of measurements.
- **Eye-tracking:** consent checking and administrative questions surrounding the eye-tracking tasks.

- **Child observations #1:** administrative fields for interviewers to complete during 6 month child observations, including consent checking and interviewer coding conducted during the tasks.
- **Child observations #2:** administrative fields for interviewers to complete during 12 months child observations including consent checking, and interviewer coding conducted during the tasks.
- **Saliva:** administrative only, not completed with participant. Covers electronic data entry of the saliva collection sheet completed by hand during saliva collection. Keyed at Reception.
- **Reception (During):** administrative only, not completed with participant. Covers data entry of the urine collection sheet for cases where a urine sample was not collected from the baby in anthropometry. Keyed at Reception.
- **Reception (Out):** short exit interview, checking of contact details and availability for a post-clinic feedback interview and administration of travel expenses.

10.3.3 Open fields for interviewer comments

As this was a pilot, it was important to collect interviewer comments during the clinic assessments. The CAI was developed so that interviewers were able to electronically record comments and feedback either:

- by making a remark at any point during electronic data collection, or
- by keying their comments into open fields included throughout the questionnaire and at the end of each station module.

Interviewers were also given a paper copy of the Daily Appointment Sheet to hand-record comments.

10.4 Redmine for content management and version control

10.4.1 Requirement for content management system

For complex studies it is advisable to develop and maintain a good system for content-management. This becomes more apparent for longitudinal studies where questions are often carried across numerous sweeps and the structure and content of the questionnaire can be complex.

As delivered, there was nothing in the specification that catered for the management of the questionnaire and SOP content. At the first meeting between UCL and NatCen there was discussion about using a content management system to manage more effectively the content of the questionnaires, not only for the pilot but also for the main stage. This type of system would enable a record to be kept of changes and sign-off.

10.4.2 Options and Implementation

Two options for such a content management system were discussed: Sharepoint and Redmine. SharePoint is used at UCL but not at NatCen so was ruled out. As NatCen had been a user of Redmine on another large-scale project and UCL said they could

host the system, the decision was to use Redmine was a joint one as it benefited both parties and met the requirements for content management and sign-off.

At a meeting between key users and IT experts at UCL and NatCen, the overall structure for the account was discussed, including procedures for raising issues, user permissions, document versioning and notification settings.

10.4.3 Function of Redmine for Pilot development

Redmine was used throughout the duration of the Pilot to record and track development and sign-off of the following elements:

- development and sign-off of the SOPs
- development and sign-off of the pre-complete questionnaires
- development and testing of CAI content.

10.5 Multiple births, proxy partner questionnaire, feed forward data

For the main stage Life Study will aim to include and track families with multiple births (twins, triplets etc) and also have a partner proxy interview. In addition, from Sweep 2 onwards the questionnaire will need to 'feed forward' certain data items from previous sweeps. These elements were not included in the pilot and so will need to be carefully tested at a later stage.

10.6 Testing of CAI programme

10.6.1 Testing timetable

Sign-off on the questionnaire content was timetabled for mid-October, around a fortnight before the start of data collection. Extra time prior to launch was required as the questionnaire content had to be manually loaded and tested on the remote server. Having an ambitious overall timeline and late delivery of final content left limited time for testing by NatCen and UCL, despite additional resources being allocated to programming by NatCen. This was due to several reasons, including the larger than expected volume of questionnaire content to program, and the reassignment of content between CAPI/CASI modes and sweep/respondent type in the revised module specifications.

During the testing phase, due to time constraints, there were limitations to the level of changes that could be made to the questionnaire. Therefore the focus for testing was to ensure that the questionnaire was fit for purpose, which was identified as:

- questions being directed at the correct participant types during the visit
- CAPI/CASI set up to allow participants to answer using the correct response categories, e.g. codes or open (as specified)
- measurement stations collect measurement data
- clinic menu system set up to receive participant data from CATI recruitment.

First modules were available for UCL testing on 19 September 2013. See Section 10.6.5 for further detail on UCL testing. As expected, a small number of minor post-testing amendments were made to the questionnaire during the interviewer training phase. These were exclusively amendments to administrative and practical elements of the CAI content.

10.6.2 Testing CASI using the touch screen monitor

As the CASI had been developed for use on a touch screen monitor, testing using a wide-screen monitor and a Windows 8 machine was required. This ensured that the questions displayed properly and worked in the same environment as they would be offered to participants. NatCen loaned UCL a touch screen device to enable testing of the CASI to be conducted at ICH.

10.6.3 Internal testing

A phased approach was used for CAI testing, starting with NatCen researchers carrying out an initial test of the programmed content against the module specifications (split by sweep). This ensured that the correct questions were being asked at the correct sweep and of the correct respondent type. CAPI and CASI were tested separately.

Stage 2 of the testing involved a more thorough test of the routing within each module. Programmers produced a version of the questionnaire which enabled testers to select individual modules (together with any inter-dependent modules) for testing without the need to complete the whole questionnaire each time.

For internal testing, NatCen researchers and programmers used Bluemine (similar to Redmine) as an issue management tool to enable tracking of queries and amendments required during testing of the CAI questionnaire.

10.6.4 "Off-spec" changes

During the questionnaire specification and programming, NatCen were asked to remain faithful to the original questions set out by the SSC. Thus NatCen were not required to undertake any systematic review of the questions or to suggest changes to questions as might happen during the early stages of a survey.

In mid-September, UCL agreed that NatCen could make some changes to the programme where NatCen felt it was appropriate. In order to action this in a timely manner and track these amendments should UCL wish to update their specifications, a separate record of 'off-spec' changes was created. These were recorded in an Excel spreadsheet, which was sent to UCL together with the accompanying modules when they were ready for UCL-testing. This list included changes that had been implemented or were to be implemented.

10.6.5 UCL testing

Updated versions of the questionnaire modules for testing were transferred to UCL via the secure FTP site. The accompanying spreadsheet of 'off-spec' changes was sent via email along with update emails on the testing process.

Given the limited time for making amendments within the timetable, it was essential that amendments were prioritised. Therefore all amendments were assessed and prioritised internally at UCL before being passed on to NatCen via Redmine.

Once the overall CAI program was finalised at NatCen, including the administrative measurement modules, UCL carried out a final test to ensure that their essential amendments had been implemented and that the final CAI instrument was 'fit for purpose' of the pilot data collection. UCL had limited time for this final testing.

11 Pre-complete questionnaires

11.1 Background and development

The decision to conduct some of the questionnaire content as a pre-visit paper self-completion exercise was made on the basis of (a) having too much content within the clinic visit and (b) the type of questions to be covered.

Separate versions of a self-completion booklet were produced for M6 and M12 participants to fill in and bring to the clinic.

- Pre-complete comprised a 14 page A4 booklet of around 60 single or multi-coded questions.
- There were two versions of the pre-complete questionnaires: one for M6 participants and one for M12 participants.
- The content for the questionnaire was specified to NatCen on 22 July, with the exception of the Ages and Stages Questionnaire (ASQ), which was provided to NatCen on 7 August.
- The content largely consisted of questions from the Word specifications including a set of questions from the ASQ, which required a licence for its use (see section 11.1.2 below).
- The questionnaire covered topics such as child sleeping and crying, diet and nutrition parenting and child development.
- The pre-complete questionnaire was printed by NatCen, a serial number barcode label was attached and posted to M6 and M12 participants with their appointment letters in a C5 size envelope. Participants were asked to bring the completed questionnaire to their clinic appointment.
- The questionnaires were collected from participants at Reception on arrival.
- Spare copies of the questionnaires were available at Reception if needed. If participants did not bring their completed questionnaire to the clinic, they were asked to complete it during their visit.

11.1.1 Formatting of pre-complete

Pre-complete questions were contained in the template module specifications provided to NatCen together with a copy of the original questionnaire instruments that the questions were being extracted from. For some components (Baby Eating Behaviour Questionnaire (BEBQ) and MORS questionnaire) it was necessary to retain

the original format but other questions could be formatted according to NatCen's usual self-completion template.

11.1.2 Ages and Stages Questionnaire (ASQ)

The inclusion of the Ages and Stages Questionnaire (ASQ) presented additional considerations for formatting and use:

- The ASQ required a license in order to view the questions and print the content on NatCen premises.
- UCL purchased a license and provided NatCen with a CD-ROM containing the ASQ questionnaires.
- The CD-ROM provided contained sets of the questionnaire. It was agreed that NatCen should include Set A, pages 2-4 of the 6 month ASQ for the M6 version and Set A, pages 2-4 of the 12 month ASQ for the M12 version.
- Due to license restrictions, no amendments could be made to the ASQ content or format, therefore the relevant pages had to be printed from the original ASQ CD-ROM. The specified ASQ pages were printed separately from the main questionnaire and slotted within the main booklet to ensure no alterations were made.
- Reservations around scalability for use on the main stage were fed back to UCL.

11.2 Pre-complete response

- All M6 and M12 participants returned their booklet at the clinic; four from M6 participants and five from M12 participants.
- Eight questionnaires were completed prior to the clinic visit and one completed by a participant during the clinic visit.
- Questionnaires took between 10-20 minutes to complete (information taken from post visit telephone feedback interviews (Section 19.3).
- Completed questionnaires were sent to NatCen's Brentwood office for data processing.

12 Post-visit survey question (M6 only)

For M6 participants only, there was an open-ended post-visit question included on the back of the thank you letter. The thank you letter was given to participants in their participant packs to take home with them. Participants were provided with a prepaid envelope for return to Brentwood.

No completed post-survey questions were received at NatCen.

13 Measurements and Training

13.1 Measurement Protocols/SOPs development

13.1.1 Overview

NatCen were provided with a set of Standard Operational Procedures (SOPs) for all measurements and observations to be undertaken on the Life Study pilot. SOPs were received at various time points between March and September 2013. Initial SOPs were received on the understanding that further work was required to build them into working protocols. To effectively understand, develop and finalise SOPs, NatCen highlighted the need to receive training on the protocols from experts and have full access to all equipment in good time, especially equipment that was unfamiliar to NatCen.

Measurements covered by the Life Study pilot were:

Table 13.1 Measurement summary

	Mother M28	Partner P28	Mother M6	Baby B6	Mother M12	Baby B12
ANTHROPOMETRY						
Weight	✓	✓		✓	✓	✓
Adult BIA	✓	✓			✓	
Adult height	✓	✓			✓	
Infant length				✓		✓
Adult sitting height	✓					
Adult waist circumference		✓			✓	
Triceps and subscapular skinfold	✓	✓		✓	✓	✓
MUAC	✓	✓		✓	✓	✓
Infant head girth				✓		✓
Fitting of accelerometer					✓	
VISION						
Eye examination (plusoptiX)	✓	✓				✓
Photograph of eyes	✓[1]	✓[1]				✓
Stereovision (Frisby test)	✓	✓				✓
CHILD OBSERVATIONS						

[1] Dependent on PlusOptix reading

Table 13.1 Measurement summary						
GAP Task (eye-tracking)				✓		✓
Mother still face				✓		
Restraint in car seat				✓		
Restraint in high chair						✓
Mother-baby interaction				✓		
Joint attention						✓
BIOSAMPLES						
Infant urine				✓		✓
Infant saliva				✓		✓

13.1.2 Development of SOPs

Following review of the SOPs NatCen highlighted gaps and suggested changes based on their previous experience of developing and implementing protocols for use in the field. The purpose of suggested changes was to create a set of cohesive instructions for interviewers to use in the clinic, to protect participants and to ensure the accuracy and robustness of the data collected.

UCL discussed proposed changes with experts to verify that these did not invalidate any measures. An iterative process ensued and key changes made in collaboration with UCL were as follows:

- A consistent tone and standard format/ordering implemented across all SOPs to enhance usability by 'non-experts'
- All equipment and consumables for each task documented as a checklist
- Changes in equipment/consumables where recommended
- Eligibility and exclusion criteria documented to protect participants
- Clear preparation and safety instructions for participants documented (i.e. where clothing is to be removed etc).
- Clear sign posting and illustrations where necessary
- Recommendation of range checks to improve the robustness of the data.

Following review and sign off from experts, UCL formally signed SOPs off on Redmine. The final SOP was signed off on Redmine on the 11th November 2013.

13.2 Expert sessions

During SOP development NatCen researchers were provided with the opportunity to meet the Vision experts and the Eye Tracking experts. The purpose of these sessions was for the expert to explain to NatCen how the device/equipment works, provide background to what they are aiming to do and allow NatCen the opportunity to ask any questions. The first of these sessions took place on the 4th July when the Tobii Eye tracking equipment was delivered to NatCen's Brentwood office; the second of these sessions took place on the 1st of August when the PlusOptix equipment was delivered. Expert sessions were not provided for child development observations, or urine or saliva bio-sample collection.

Meeting with the experts was fundamentally important for helping NatCen to understand how the IT and equipment might be set up to interface with the NatCen network once in the clinic, as well as gain an understanding of how the data would be captured from each device. Sessions were also important for understanding how the measurements might be operationalised in the clinic and helpful for providing contextual information about how the protocols vary when working with babies. NatCen subsequently amended the eye tracking SOP to incorporate guidance to interviewers about deviations to the protocol when working with babies.

During expert sessions, certain pieces of equipment (such as the hydraulic arm, black cloth, pinhole glasses, a web cam and toys for both eye tracking and vision) were identified as outstanding. These items were fundamental to the protocol and were subsequently ordered by UCL. The vision experts also requested the addition of a focimeter and printer to the vision protocol.

13.3 'Train the trainer' sessions

Train the trainer sessions were held between the 11th September and the 19th September 2013. The aim of the sessions was to train the three Nurse Supervisors (recruited from NatCen's interviewing pool of trained nurses) who were taking on the role of Clinic Supervisor. This role included managing the clinic shifts, managing the interviewers and ensuring the measurement protocols followed. In practice they also conducted the saliva collections.

Experts were invited to train the Clinic Supervisors in the administration of the protocols. NatCen recruited six babies to attend the sessions so that experts were able to effectively demonstrate infant protocols to Clinic Supervisors. It was not possible to obtain access to the pilot venue at this stage therefore demonstrations took place at NatCen offices. The manufacturer had previously provided training on the Bio Impedance Analysis (BIA), but the expert had not used the specific piece of equipment before. Experts provided training for height, infant weight or urine collection but again were not familiar with the actual equipment that was being used.

The 'train the trainer' sessions were helpful in ironing out final changes to the protocols (particularly for child observations, bio samples, adult anthropometry and infant anthropometry) as this was the first time that NatCen had the opportunity to meet with the expert leads for these SOPs and see a demonstration on an infant.

A member of the UCL Life Study team attended all training sessions.

Other key issues to emerge from the train the trainer sessions were:

- Hygiene and safety hazards: Various health and safety risks were noted in the sessions for example babies chewing on equipment and toys and the corners of a rug curling up. This highlighted the need for spare equipment and cleaning/sterilization/safety consumables to be made available in the clinic.
- Participant flow: Training sessions were organised around infant nap and feeding times. Infants in attendance were there for a minimal period of time (about one hour) yet still struggled to remain fully engaged in some tasks for the duration. Experts agreed that the order in which babies attend each station in the clinic and whether they are tired/hungry will significantly affect how they perform in each task.

- Equipment:
  - Following the training session the measuring tape for 'waist' circumference was replaced with an 'easy check' circumference tape to allow for a more accurate reading. The Life Study team updated the 'waist circumference' SOP accordingly.
  - UCL confirmed that the cotton wool balls used for urine sampling in the pilot would not be the type used in the main stage. As further pilots of the baby visits will be undertaken at later stages this is not a significant issue.
- Infant engagement: During the child observation and vision assessment training it became apparent that certain tasks would benefit from a 'warm up period' to allow the infant to become familiar both with the interviewer and the task. Subsequently an engagement task was introduced for the 12 month child development observations and a familiarisation task was implemented for the Frisby test in the Vision assessment.
- Disposal of biological samples: At the time of the 'train the trainer' sessions disposal and transport procedures for biological samples had not been finalised. NatCen highlighted the benefit of testing these procedures prior to the main stage.
- Time thresholds: The 'train the trainer' sessions were the first opportunity to see a demonstration of the saliva SOP on a baby. The procedure was quite lengthy during the demonstration therefore the decision was made to introduce a threshold of 10 minutes in the clinic to avoid very long waiting times.

13.3.1 Issues

The final version of the bio sampling SOPs (saliva and urine) were received on the 15th September leaving little time to develop the associated materials and test the methodology and equipment. Similarly the development of a SOP for infant vision was raised during train the trainer sessions.

Following 'train the trainer' sessions key decisions or changes were commonly made such as the introduction of new equipment or consumables which necessitated a reworking of the SOP. For example, the focimeter for the vision assessment had not been written into the original SOP and was delivered very close to fieldwork launch. It was also discovered that the PlusoptiX device did not operate in uniocular mode. It was not possible within the timescales to update the vision SOP to remove uniocular mode from the protocol which meant that the final SOP was confusing for interviewers during training sessions.

Development of the SOPs was a joint effort involving Life Study team, experts and NatCen. This required researchers at UCL and members of the NatCen team to become familiar with complex and new pieces of equipment or concepts.

For some measures, NatCen felt that they would have benefited from having more direct communication with experts at an earlier point. With the exception of Vision and Eye Tracking, the communication chain between NatCen, UCL and the experts was indirect. NatCen had to operationalise these measures and train their fieldwork staff to use the equipment and receiving training from and having direct communication with experts at an earlier point would have helped to ensure that NatCen researchers had a better understanding of the equipment, the procedures and how the procedure is administered on a baby.

13.4 Interviewer Briefings

A team of experienced NatCen interviewers were selected to conduct the pilot data collection. A full day 'Theory' briefing led by members of the NatCen research team was held on the 17th October (not at the pilot venue as access was not available). Nineteen interviewers were briefed on the background to Life Study, Reception, CAPI, CASI, the structure of the clinic visit, some anthropometric measures and general house keeping. The purpose of the theory day was to cover essential elements in advance of gaining access to the pilot venue therefore maximising time within the clinic for demonstrations and practice. At the theory day interviewers were provided with SOPs and encouraged to read through them prior to practical days.

Practical days were held on the 20th, 26th and 27th October in the Clinical Research Facility (pilot venue). Due to the breadth of information to be covered interviewers were split into skill-set groups to be trained as 'specialists' on particular stations. On the 20th October 17 interviewers were (according to their allocated group) trained in adult anthropometry, adult vision, reception and set up/close down procedures. On the 26th and 27th of October 10 interviewers and 9 interviewers respectively were trained in infant anthropometry, child observations, the baby vision assessment, baby eye tracking and reception (according to their allocated group). In each practical session interviewers were familiarised with equipment, walked through the SOP step by step and provided with an opportunity to practice. As all interviewers were not available on both days material covered on the 26th was repeated on the 27th.

In total 21 NatCen interviewers attended a briefing and carried out work on the study.

13.4.1 Issues

NatCen were unable to gain access to the CRF to set up the necessary IT (Access Points, dedicated server etc) until the 19th October. This had implications for training as it was not possible to resolve initial problems with WiFi connectivity by the first practical briefing on the 20th. Subsequently interviewers could not be trained on some measures in the allocated rooms and demonstration of the measurement CAPI and some equipment had to be omitted due to connectivity issues.

Interviewer availability and limited access to the clinic and equipment meant that there was insufficient training time in the Clinical Research Facility for interviewers to gain practical confidence in the measurements. This was particularly the case for interviewers who were tasked with administering complex measures such as eye tracking, vision and child observations. Training time was further shortened by time spent setting up and closing down equipment at the beginning and end of each day. Interviewers commented in their feedback that time spent setting up and closing down detracted from their learning and understanding of the SOP.

It also became clear during the course of the pilot that many interviewers who did not have a clinical background (e.g. nurse, paramedic, etc) were not fully confident in practical measurements even by the end of the pilot. There were a number of reasons for this. There was a low throughput in the clinic, which meant that interviewers (who were working shifts, and so were not there every day) had limited chances to put their training into action, and so did not reach a level of expertise where they could feel fully confident in what they were doing. Interviewers also had to spend a lot of time and effort working out how to set up the equipment properly for each shift and then pack it up again, which took time and resource away from their actual training and ability to

use the equipment. Both of these issues should not arise for the main stage, which will help ensure that non-clinical staff (if used) would be able to reach a sufficient level of competence.

However, it is clear that some fieldworkers (both clinical and non-clinical) found the tasks more difficult than others. It will be important at the main stage to monitor the quality of staff and to ensure that those who are finding tasks challenging are provided with further support, or are taken off the project.

14 Equipment and IT development

14.1 Integration of equipment

Equipment used in the clinic was a combination of NatCen and UCL equipment. It was necessary for NatCen to gain an understanding of the specialist equipment and where possible interface everything within the specially devised clinic visit IT system. This was achieved in the using Blaise software as a framework. All data was captured and saved onto one central server housed at the pilot venue. Ideally the data would also have been able to be backed-up to the NatCen server but as no ADSL/Internet connection was available this could not take place during the pilot.

14.2 CASI touch screen development

14.2.1 Hardware

A Blaise mode library was used to facilitate development of a touch screen CASI within the Blaise environment. NatCen purchased one touch screen monitor and Windows 8 machine and awaited client sign off on the monitor before purchasing the remaining three further monitors and machines. The make and model of touch screen purchased for the Pilot was:
Make: ViewSonic TD2220
Model: VS14833
PC Operating system: Windows 8

NatCen loaned a touch screen and Windows 8 computer to UCL for CASI testing.

14.2.2 Programming and formatting of CASI content

Available options for formatting within the Blaise environment were reviewed. During the early stages of programming, a demonstration of the CASI showcased the touch screen monitor functions and formatting options.

Following the CASI demonstration a document outlining formatting options was developed and reviewed. Given the short timescale for development, it was necessary to prioritise the CASI formatting requirements, categorising each request as either ‘essential’, ‘preferable’ or ‘to be considered for the main stage’.

The grids in the environment module were particularly difficult to program, given the complex layout. No filtering rules were applied to grids for the Pilot.

14.3 Verification process

As the pilot required participants to move between various measurement stations, it was essential to build into the data collection a verification process to ensure all the data for each participant was collected and stored under the correct serial number. A sheet of barcoded labels was produced for each participant. A label was attached to every paper document (coding sheet, print out, pre-complete etc) for each participant which allowed all the paperwork to be correctly attributed to the correct respondent. In addition, at the start of each assessment (vision, CAPI, CASI etc) interviewers were instructed to scan the participant barcode (using a barcode scanner). This displayed on the laptop the participant's name and DoB which was then verified with the participant before moving on to the set of measurements to be collected at that 'station'.

15 Recruitment

15.1 Introduction

A proposal for the recruitment process and generation of the sample file was developed in communication with UCL. Prior to starting recruitment NatCen and UCL met on a weekly basis to discuss developments and make decisions.

15.2 Eligibility criteria and sample targets

The eligibility criteria were defined and refined in the weeks leading up to recruitment. Expectant parents (M28 and P28) were eligible to take part in the pilot at any point after the mother had been for her 20 week foetal abnormality scan. It was decided that babies in the M6 group needed to be aged between 4 and 8 months at the time of the clinic visit; those in the M12 group between 10 and 14 months. It was agreed that, where possible, M28 and P28 couples would be matched in the sample file; however, fathers whose partners weren't part of the study could participate if desired.

NatCen highlighted a number of potential risk points for sample loss. These included waiting periods between the initial meeting with UCL staff and NatCen's call, waiting time between sending out the PIS and NatCen calling to make an appointment, and time between appointment booking and the appointment itself. This meant that to ensure that the target numbers visited the clinic would require far larger numbers to be approached and recruited.

15.3 Recruitment process

Recruitment for Life Study clinic visits began on the 28th August 2013. The UCL Life Study team took responsibility for recruitment and the process met the requirements of NHS research ethics and governance approvals. The appointment booking process was coordinated by NatCen's Telephone Unit. Posters were placed by UCL at London

antenatal clinics and children's centres, and online at well known parenting websites. There were two main recruitment routes:

- Route A - initial contact with a UCL representative and completion of a consent to contact form;
- Route B - direct contact with NatCen's Telephone Unit (TU) using the Study's dedicated freephone number or email address.

The recruitment process operated in the same way for the four sample groups: M28, P28, M6 and M12. However, there were small differences in that direct contact with the UCL staff member took place at UCLH's antenatal facility for M28s and P28s, and in parent and child groups for M6s and M12s.

Where there was direct contact between UCL staff and potential participants, the Life Study representative gave an introduction to the study and explained the two alternative contact options – completing a 'consent to contact' form, or contacting NatCen directly.

For parents joining the study via Route A recruitment typically involved taking the opportunity to hear more about the study from a UCL representative and completing one of the Life Study's paper 'consent to contact' forms. The form collected name, address and telephone contact details, as well as due date/ child's date of birth, and recorded whether they had taken a Participant Information Sheet (PIS). Completed 'consent to contact' forms were placed in an envelope, given to the same member of the UCL team and then sent to NatCen by 1st class recorded delivery (signed for by operations staff at NatCen's Brentwood offices).

Giving 'consent to contact' was not a commitment to take part in the pilot, merely agreement for contact details and clinical information (i.e. that a woman was pregnant) to be passed to NatCen.

Although many of the parents who had spoken to a member of the Life Study team opted to complete 'consent to contact' forms, others choose to join the study via Route B – contacting NatCen directly.

Once the completed 'consent to contact' forms had been received by NatCen these were keyed into the sample file. This formed a database for the telephone unit to make contact, confirm the PIS had been read and understood and book appointments. Where participants had not already seen a PIS this was sent out by the telephone unit prior to booking the appointment.

Typically, Route B participants contacted NatCen having seen one of the advertisements in UCLH or on the internet. Initial contact was made by email and the Participant Information Sheet sent as a PDF document. Once participants indicated that they had read the PIS, they were asked to provide a contact number. At this point the TU made telephone contact, collected contact details and booked the appointment.

Information was recorded about all potential participants making email contact with the Telephone Unit. The spreadsheet included fields for participant type, the date the initial email was received, notes of actions taken and outcomes. This information was used to monitor response and reasons for refusal among those making email contact (Section 15.8).

Some participants were asked to provide feedback on the recruitment process in a post clinic follow-up interview (Section 19). Interview data suggested that the process worked well. Route A respondents were positive about their contact with UCL staff, who they found friendly and approachable, and found the 'consent to contact' forms easy to complete. They were also positive about the length of time between completing the form and receiving a phone call from NatCen, although one participant thought this time might usefully have been shorted to three days. Participants also suggested that more information about the study could be given at initial contact, for example, more about how the data would be used, and how long visits would take.

"*It would have been helpful if the member of staff who was recruiting had explained exactly what the study was all about, how long it would take and that it would be necessary to bring your own lunch*".

It is important to highlight that active 'recruiting' at the antenatal clinic by the Life Study team member was not permitted under the REC ethics approval as the Life Study staff member was not part of the hospital clinical care team. Life Study team members were restricted to providing an opportunity for interested potential participants to volunteer their contact details by completing the 'consent to contact' form, and to providing information (including a PIS) for women to pick up if they wished. Ideally there would be more active recruitment at the main stage.

Route B participants had heard about the study from a number of different sources, including: an email from UCL, an advertisement on NetMums, friends passing on information, webforums for new parents and the ESRC website. Feedback about the advertisements was generally positive, although there was a mixed response to the amount of information provided – with some participants wanting more detail about the study (for example, expected length of visit).

Although email proved a popular way of making initial contact, one interviewee suggested that this be extended to online registration. This would mean that contact details are collected and stored electronically – making collection systematic and limiting potential errors when recording contact information.

15.4 Partner recruitment

It was anticipated that P28s would primarily be recruited via Route A with initial contact taking place at antenatal clinics (while accompanying partners to appointments), but could also be recruited independently via Route B. Advertisements were placed on websites and forums for fathers and in facilities for young children that fathers attended.

In practice, however, partners were only recruited through expectant mothers, none of them having initiated the clinic visit themselves. Post clinic follow-up revealed that P28s had a very low awareness of the partner-specific materials. They were generally happy to participate when made aware of study. Participation tended to be motivated by:

- A desire to support the expectant mother;
- A professional interest in the study;
- A desire to 'give something back' to UCLH; or
- A combination of the above.

P28s rarely completed their own CATI (this was done for them by M28s), verbal consent being given for participation while M28s booked appointments. A late decision to directly target the partners' of expectant mothers who expressed an interest on their behalf raised awareness and led to one additional P28 appointment being booked. In keeping with generally lower levels of engagement with the study, P28s were also less likely to have read the PIS or appointment letter.

15.5 Recruitment materials

Pilot recruitment materials were developed by UCL. Drafts were supplied to the Ethics Committee before recruitment and approval granted ahead of recruitment. NatCen supplied one round of comments on materials. All materials included the Life Study and University College Hospital NHS Trust logos.

Recruitment materials included:

- Information cards: printed by UCL to be given out at the antenatal clinic/ parent and baby groups;
- Life study bookmarks (four variants corresponding to the four participant types), with teabags: printed by UCL and supplied to NatCen, for teabags to be attached, before distribution to potential participants;
- Participant Information Sheets (PIS): A5 colour booklets printed by UCL and supplied to NatCen for distribution to potential participants. Four variants corresponding to the four participant types;
- Appointment confirmation letters: template supplied by UCL to be mail merged and printed by NatCen, before being sent to participants. Letters included appointment details, a map and directions to the clinic and a checklist of items to bring to the appointment;
- Pre-complete questionnaires: to be formatted and printed by NatCen and sent out to M6 and M12 participants;
- Life Study envelopes: printed by NatCen and used to send out the PIS with bookmarks (C4) and appointment letters with pre-completes (C5).

A printing error in the M6 PIS resulted in leaflets being recalled back to UCL for amendment and larger envelopes had to be sourced to accommodate the bookmarks which, on arrival at NatCen were larger than the mock-up version.

The post-clinic follow-up interviews included a number of questions about the materials. Comments were generally positive, although there were a number of requests for further information about timings and how to find the clinic, as well as concerns that items from the checklist weren't used at the clinic (Section 19.3).

15.6 CATI briefing

The briefing took place on 18th September 2013 and was attended by a member of the UCL Life Study team.

15.7 The recruitment CATI and serial numbers

A Computer Assisted Telephone Interviewing (CATI) programme was developed to capture information about potential participants. This included contact details, background information, and data needed to link expectant parents in the sample file.

Route A cases were already in the system's sample file and had been assigned a temporary serial number, so NatCen confirmed and, if necessary, corrected contact information before booking the appointment.

Route B cases had a new sample case and temporary serial number created for them when the initial call was made.

At the end of each day the sample file was run and permanent serial numbers created. Once the respondent had completed the CATI and made an appointment:

- Appointment letters were printed and sent to respondents. For M6 and M12 respondents a pre-complete questionnaire was also posted out with their appointment letters;
- A reminder text / email was offered when booking the appointment. Participants almost exclusively selected a text reminder. This was sent one working day before the appointment and did not appear to encourage refusals.

The appointment list was transferred at the end of every day before each pilot clinic assessment day.

Findings from post-clinic feedback interviews suggest that the CATI element of the recruitment process worked well (Section 19.2).

15.8 Response and refusals

Route A:
A total of 24 consent to contact forms were received over the course of the recruitment period. One case was found to be out of scope before an appointment was made; of the 23 remaining cases 2 participants could not be contacted, 1 was away for the fieldwork period, 7 refused and 13 made appointments. 12 of the 13 booked appointments were kept.

Route B:
Most common means of making contact was via email. Over the course of the recruitment period NatCen received 83 speculative emails about the study (compared to just one speculative phone call). Of these initial emails, 12 were either ineligible or did not provide sufficient information for us to be able to assign them to a category. Of the 7 participants deemed to be ineligible, this was either due to the age of the child or stage of pregnancy being outside that required

Although not a formal eligibility criterion, distance from the clinic was a factor for some potential participants. For example, contacts came from across, and even outside, Britain including Northern Ireland, Leeds, and Bristol.

15.8.1 Common reasons for refusal:

There were also 22 refusals among those making initial contact, but not going on to make an appointment. Not everyone provided a reason for refusing, but among those who did the reasons mentioned included:

- Difficulties finding child care for older children;
- Problems with the expected length of the visit;
- Problems with appointment times, e.g. evening appointments being too late;
- Travel difficulties / distance from the clinic;
- A combination of the above.

In addition, one mother of twins decided not to take part as measurements were not going to be taken from both her children.

Table 15.1 Recruitment response by outcome

	Route A: consent to contact					**Route B: speculative emails and phone calls**				
	M28	**P28**	**M6**	**M12**	**Ineligible or type unclear**	**M28**	**P28**	**M6**	**M12**	**Ineligible or type unclear**
Expressions of interest	**14**	**1**	**6**	**2**	**1**	**36**	**7**	**13**	**15**	**12**
Initial screening showed participant ineligible	**-**	**-**	**-**	**-**	**1**	**-**	**-**	**-**	**-**	**7**
Eligible - no appointment booked	**6**	**1**	**3**	**1**	**-**	**14**	**-**	**10**	**11**	**5**
PIS sent, further contact attempted, no response (email only)	-	-	-	-	-	6	-	3	5	2
Attempted phone contact with participant but could not speak to them directly, answer phone message left	1	-	-	-	-	1	-	1	-	-
Personal refusal to clinic visit by participant	2	-	1	-	-	1	-	-	1	-
Proxy refusal to clinic visit on behalf of participant	-	-	-	-	-	-	-	-	-	1

Table 15.1 Recruitment response by outcome										
Broken callback appointment, TU to ring back (e.g. made appt to call after PIS sent but participant not available)	1	-	-	-	-	-	-	-	-	-
Participant away or in hospital during fieldwork period	-	-	1	-	-	-	-	2	-	-
Participant could not attend any of the available timeslots	-	-	-	-	-	2	-	1	1	1
Other refusal to clinic visit (i.e. all refusals not captured above)	2	-	1	1	-	4	-	3	4	1
Appointment booked	**8**	**1**	**3**	**1**	**-**	**22**	**7**	**3**	**4**	**-**
Appointment booked - cancelled by TU, reschedule not possible	-	-	-	-	-	-	-	-	-	-
Appointment booked - cancelled by participant	1	-	-	-	-	-	1	2	-	-
No show	-	-	-	-	-	2	-	-	-	-
Interviewed, data not able to be used	-	-	-	-	-	1	1	-	-	-
Interviewed	**7**	**1**	**3**	**1**	**-**	**19**	**5**	**1**	**4**	**-**

15.9 Appointment schedule

Once the Life Study team had confirmed the venue and working hours available for set up and data collection an appointment schedule was set up for appointment bookings (Table 15.2). It was decided in discussion with UCL that weekday appointments would be restricted to M28 and P28 visits, and weekends to M6 and M12. This meant weekday set-up would be more straightforward, as the baby stations would not need to be prepared.

Table 15.2 Schedule for appointment booking			
		Maximum number of participants per shift	Cumulative number of appointment slots
Sat 19, Sun 20 Oct	NatCen on site prep/briefing day 1, 2	-	
Sat 26. Sun 27 Oct	NatCen on site prep/briefing day 3, 4	-	
Mon 28–Thu 31 Oct	M28, P28 only	16	16
Fri 1 Nov	M28, P28 only	2	18
Sat 2 Nov	M6, M12 only	10	28
Sun 3 Nov	M6, M12 only	8	36
Mon 4–Thu 7 Nov	M28, P28 only	16	52
Fri 8 Nov	M28, P28 only	2	54
Sat 9 Nov	M6, M12 only	10	64
Sun 10 Nov	M6, M12 only	8	72
Mon 11–Thu 14 Nov	M28, P28 only	16	88
Fri 15 Nov	M28, P28 only	2	90
Sat 16 Nov	M6, M12 only	10	100
Sun 17 Nov	M6, M12 only	8	108
Mon 18–Thu 21 Nov	M28, P28 only	16	124
Fri 22 Nov	M28, P28 only	2	126
Sat 23 Nov	M6, M12 only	10	136
Sun 24 Nov	M6, M12 only	8	144
Mon 25–Thu 28 Nov	M28, P28 only	16	160

Under this proposal data collection was anticipated to take around 4-5 weeks (32 interviewing days). It allowed for 160 fixed appointment bookings, including 88 pregnancy visits. In practice only 49 appointment slots were used (two of these cases were 'dummy' appointments and could not be counted towards the overall number as Research Passports were not in place at the time of interview).

Four different appointment schedules were prepared, one for weekday evenings Monday to Thursday (Table 15.3), one for Friday evenings (Table 15.4) - allowing additional time for the change over from M28 / P28 to M6 / M12, one for Saturdays (Table 15.5) and one for Sundays (Table 15.6) – again with addition time built in for changeover.

Table 15.3 Weekday (Mon – Thur) shift schedule

M28 and P28 participants only.
8 rooms/stations to set up: Reception, CAPI x 4, CASI, Vision, Anthropometry
7 interviewers per shift

Appointment time		
1500-1630	Set up and calibration. No participant appointments	
16.30	Slot 1	Slot 2
17.15	Slot 3	Slot 4
18.30 – 20.00 or until data backup and room restore is complete	No participant appointments booked. This time is for last appointments to be completed and conduct 'end of day' office activities No Biosamples collection needed	

Table 15.4 Weekday (Fri) shift schedule

M28 and P28 participants only
6 rooms/stations to set up: Reception, CAPI x 2, CASI, Vision, Anthropometry
4 interviewers per shift
Extra time needed to set up rooms for weekend interviewing

Appointment time		
15.00-16.30	Set up and calibration. No participant appointments	
16.30 finish 19.00	Slot 1	Slot 2
19.00 – 20.00 or until data backup and weekend room prep is complete.	No participant appointments booked. This time is for last appointments to be completed and conduct 'end of day' office activities No Biosamples collection needed	

Table 15.5 Weekend (Saturday) shift schedule

M6 and M12 participants only.
9 rooms/stations to set up: Reception, CAPI x 2, CASI, Vision, Anthropometry, Eye Tracking, Child Obs x 2
9 interviewers per shift

Appointment time		
09.00 – 09.30	Set up and calibration. No participant appointments	
09.30	Slot 1	Slot 2
10.30	Slot 3	Slot 4
11.30	Slot 5	Slot 6
12.30	Slot 7	Slot 8
13.30 finish 16.30	Slot 9	Slot 10

Table 15.5 Weekend (Saturday) shift schedule	
16.30 – 17.00 or until data backup complete. No room restore necessary	No participant appointments booked. This time is for last appointments to be completed and conduct 'end of day' office activities Biosample courier to be arranged by UCL

Table 15.6 Weekend (Sunday) shift schedule		
M6 and M12 participants only. 9 rooms/stations to set up: Reception, CAPI x 2, CASI, Vision, Anthropometry, Eye Tracking, Child Obs x 2 9 interviewers per shift		
Appointment time		
09.00 – 09.30	Set up and calibration. No participant appointments	
09.30	Slot 1	Slot 2
10.30	Slot 3	Slot 4
11.30	Slot 5	Slot 6
12.30 finish 15.30	Slot 7	Slot 8
15.30 – 17.00 or until data backup and room restore complete.	No participant appointments booked. This time is for last appointments to be completed and conduct 'end of day' office activities Biosample courier to be arranged by UCL	

A master paper-based schedule was passed to NatCen's Telephone Unit, who made appointments and monitored progress. A paper-based system was selected over an Outlook-based one on the basis that the appointment-making process was relatively straightforward and to be administered by a small number of interviewers.

16 Venue

The choice of venue in which to conduct the pilot data collection was made by UCL. Conducting the pilot at the Clinical Research Facility (CRF) at UCLH had several benefits for participants:

- Large, hygienic space with room to wheel around buggies.
- Central location close to several tube stations
- Availability of toilets
- Kitchen area to heat baby food including fridge in which food could be stored
- Comfortably furnished and equipped
- Suitable for disabled access, including several disabled toilets
- Ease of access to medical care in urgent situation (e.g. pregnancy complication), including on-call medical staff and emergency call buttons
- Appropriate access to local safeguarding team at UCLH for advice

- Availability of multiple power points and suitable lighting (dimmer)
- Appropriately covered by infection control measures and clinical risk assessments appropriate to NHS patient-related activities.
-

However there were a number of venue-related challenges and constraints that had to worked within:

- Late notification that Research Passports would be needed and difficulties in getting Occupational Health check appointments before the start of data collection. Use of an NHS venue meant that NHS Research Passports were needed (including Occupational Health check appointments) for all interviewing staff before the start of data collection.
- Potential hazards for young children: open sharps boxes present on more than one occasion, trays of needles and other clinical consumables, lots of other equipment on display with exposed cables and wires
- Limited time available during weekdays (3pm – 8pm)
- Limited time available to access the server on weekdays (3-3.30 and at other time by prior arrangement)
- Inconsistent WiFi connectivity resulting in intermittent dropped connections and data loss
- No ADSL/Internet connection throughout Pilot resulting in extra on-site IT and Project Computing cover needed.
- Not able to keep equipment permanently set up.
- Measurement rooms not always free on arrival at 3pm

- Tea/coffee and biscuits were provided for participants. Additional food was not provided to participants as it was not foreseen that appointments would overrun. At some weekend sessions, food (sandwiches) was provided ad-hoc from CRF patient stores or by the Life study team member.

- Life Study team members delivered the six equipment cages from storage when they arrived on shift at 3pm. This could result in a delay of 5-15 minutes in delivering all cages if the Life Study team member had no assistance. Interviewers and NatCen staff unloaded the cages and equipment setup commenced as soon as one cage of equipment was delivered. No appointments were delayed due to late delivery of equipment.

Within the operational constraints, the pilot clinic set-up included:

- Safe-guarding policy (as provided by the Life Study Team and UCLH)
- Risks and Issues Log for recording notable events
- Daily activity sheet for CRF staff showing name and appointment details for each participant interviewed for the pilot
- Set up of a dedicated server (with on-site back up drives) to store collected data from a number of different measurement devices

16.1 Research passports: OH clearance, data confidentiality

16.1.1 Research Passport application process

In mid-September NatCen were advised that all interviewers and researchers involved in data collection or handling participant-identifiable data were required to have a valid Research Passports in order to undertake data collection on NHS premises at the CRF. Since then there were further requests for different forms and procedures to complete the process. All members of the NatCen data collection team, including interviewers and researchers were required to undergo the following procedures during the application process:

- Completion of Research Passport Application Form
- Completion of UCL Institute of Child Health honorary contract/Visitor request form
- Provision of an up-to-date CV
- Provision of two work-based references
- Occupational Health check(s) (section 16.1.2)
- Completion of a Job Hazard form. (completed by UCL on NatCen's behalf)
- Proof of identity including sight of original document and photocopy for UCL
- Provision of scanned copy of DBS certificate to UCL
- Proof of qualifications obtained if available

16.1.2 Occupational health checks

One part of the Research Passport process to enable interviews to be conducted at the CRF involved NatCen interviewers and researchers needing to undergo Occupational Health (OH) checks and to provide proof of immunity to TB, Measles, Rubella and Chicken Pox. . This was to ensure that participants, in particular unborn babies and children, would not be placed at risk through contact with research staff.

All interviewers (and researchers) were required to attend a face-to-face appointment at Gower Place Health Centre with potential follow-up appointments 7-10 days later depending on results of blood tests. Availability of OH appointments was limited and many interviewers were given first appointments a day or two before their first shift – and some as late as 13 November.

Interviewers were given priority over researchers for OH appointments and regular updates were provided to UCL throughout the Research Passport application.

16.1.3 Implications for timetable

The original start date for data collection was 21 October. As the minimum set up time at the confirmed venue had not been met the start date was pushed back to 28 October.

Despite this, the late and numerous requirements for Research Passports resulted in having insufficient interviewers with a valid Research Passport in place in order for

early appointments to be kept. Consequently 3 appointments scheduled between 28 Oct and 3 Nov had to be rearranged. Two participants who attended their clinic appointment scheduled for 31 October (M28, P28) agreed to act as 'practice participants' (these participants were made aware that data would not be included in the final dataset).

Research Passports were issued to interviewers gradually when they became available. All interviewers and researchers who applied were issued with Research Passports and these were issued between 4 November and 17 November.

Despite a limited number of interviewers being issued with Research Passports until mid-November, NatCen ensured that data collection could commence from 4 November when the first batch of Research Passports were issued.

16.1.4 Confidentiality of Interviewer data

Many of the Research Passport application documents being transferred from NatCen to UCL contained personal details of interviewers and researchers and were treated by NatCen in accordance with the ISO27001 standard. Scanned documents were transferred to UCL via an FTP site for UCL download. Photocopies of identity documents were delivered to a UCL team member by hand.

17 Staffing

17.1 Resourcing

The staffing model was devised based on the expected throughput of participants, the expected interview length (2.5 – 3 hours), the working hours available at the pilot venue and the need to set up and pack away the equipment at the start and end of each shift. We understand that the model in the main stage is likely to be different.

Table 17.1 Pilot staffing model

Day	Expected throughput of participants (per day)	Actual throughput of participants	Hours per shift	No. of interviewers per shift	No. of shifts in pilot
Monday – Thursday	4	0 – 4	5	7	20
Friday	2	1 – 2	5	4	4
Saturday	10	0 – 4	8	9	4
Sunday	8	0 – 3	8	9	4

Due to the low level of recruitment on several days the clinic was 'over-staffed' with the number of interviewers out-numbering the number of participants. A finding from the feedback calls was that some participants felt as though they were 'being watched'. Again, this is unlikely to be an issue for the main stage.

During the start of the pilot data collection, on days where there were no participants booked interviewers took the opportunity to practice the adult measurements on each

other. Towards the end of the pilot it was suggested by NatCen that the clinic session should be cancelled to save on interviewer travel expenses. One weekday and one weekend shift were cancelled with the agreement from the Life Study team. One further weekday shift was cancelled without permission from the Life Study team and the cost of that session covered by NatCen.

18 Pilot clinic sessions

Preparations for each pilot clinic included:

- Loading the pilot sample onto the on-site server. This had to be done in person as remote access was not available.
- Personalised participant materials taken in person to the CRF by the research manager covering that shift
  - Cash in pre-prepared envelopes to cover participant travel payments
  - Daily appointment sheet: daily schedule of appointments booked, including time of appointment, participant name and respondent type
  - Participant packs: individualised packs containing participant summary sheet (with clinic flow), barcode labels, thank you letter, GP letter, M6/M12 packs also contained urine collection sheet and saliva collection sheet
- Assigning interviewers to specific data collection 'stations' on the basis of which interviewers had their Research Passport at the time
- Unloading of equipment and setting up each measurement station in advance of arrival of the first participant

End of session tasks included:

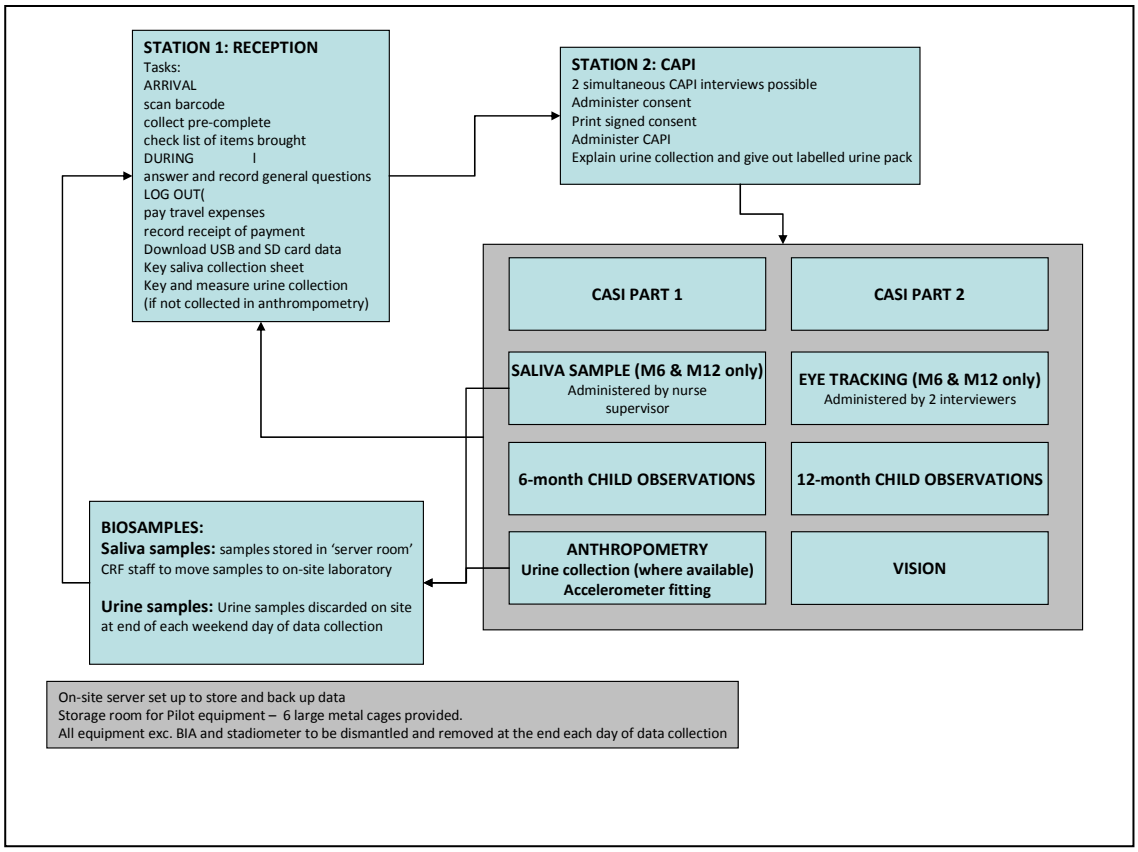
- Back-up of data from anthropometry, consent and PlusOptiX machines
- Safe close-down and packing away of every item of pilot equipment including loading equipment onto six large metal cages which were initially stored out of hours off site, and eventually in a large secure storage room within CRF building, as arranged by UCL. During the Life Study clinic hours, cages were placed in an unused patient bay across which a curtain could be drawn (see Figure 18:1).
- Swapping over the external back-up drive for the server
- Completion of Activity Sheet and other necessary paperwork
- Short catch-up session with Interviewers and UCL representative to cover issues arising
- Sign off by UCL representative that (a) the server room door was locked and (b) CRF was left in a satisfactory condition on NatCen departure

Figure 18:1 Equipment storage in the unused patient bay

18.1 Flow around the clinic

Figure 18:2 shows the possible flow around the clinic. Fixed elements were Reception (on arrival), CAPI (to collect consent and complete the household grid) and Reception (on departure).

Figure 18:2 Flow around the clinic



18.2 Fixed v. flexible flow

As part of the development for the main stage a more detailed understanding of the optimum flows is essential. For the Pilot, NatCen were given a series of fixed flows templates to follow based on the respondent type and appointment times.

NatCen suggested a semi-flexible flow was adopted to allocate participants to the various stations at the clinic on the basis that:

- Beyond Reception there was no enforced order between measurements stations (areas in grey)
- Throughput for the pilot was lower then anticipated and therefore having an enforced flow would needlessly increase overall visit lengths

The fixed flow approach sometimes resulted in bottlenecks, particularly between anthropometry and vision. Where this occurred the NatCen researcher at the clinic allowed a maximum waiting time of 5 minutes for each participant before introducing the flexible flow approach.

However, it is hard to draw any conclusions from this for the main stage, given that the staffing model is likely to be different and the physical space will be bespoke for the needs of the Study. It will be important to do more testing when the staffing model and physical space are known.

19 Participant feedback

19.1 Introduction

At the end of the pilot interview participants were asked if they would be willing to be re-contacted for a short post-clinic telephone call to get their feedback on their experience. The intention was to call a selection of participants, focussing on partners, mothers who were fitted with an accelerometer and those who arrived early/late or didn't complete the full visit.

Follow-up calls were conducted with 24 of the Life Study pilot participants (twelve M28s, six P28s, four M12s and two M6s). Interviews were conducted by 3 researchers: all with varying first-hand involvement with the pilot development and/or clinic set-up. Telephone interviews took around 30 to 40 minutes depending on the participant type. Interviews with M6s and M12s typically took longer because there were a greater number of measurements to cover.

Semi-structured telephone interviews took place between 11 November and 3 December and conducted using a topic guide covering recruitment, materials, and measurements in the clinic and thoughts/feelings after leaving the clinic. A copy of the topic guide is included in the appendices to this report. All themes are covered below.

It is important to note that a set script and questions were not used as part of this process, and so we have not reported the numbers or percentages saying specific things, as not all participants were asked the same questions. Where we quote participants directly quote marks have been used.

19.2 Recruitment

UCL were responsible for distributing participant recruitment materials. Participants were recruited for the pilot by two different means: Route A whereby participants completed a consent to contact form at the UCLH antenatal clinic, and Route B whereby participants had seen an advert for the Study either on a website, poster or via email and had made direct contact with NatCen.

Motivations for participating via route A were commonly driven by personal interest due to working in research or clinical trials and wanting to 'give something back'. Participants also commented that they wanted to help out as UCLH had been very supportive during their antenatal treatment.

Motivations for participating via route B were that the Study "sounded interesting", the participant "wanted to help out" and particularly interested because it's one of the few prospective longitudinal studies.

Common themes about the recruitment process were:

Route A (UCLH consent to contact form)

- It would have been helpful if the member of staff had explained exactly what the Study was all about, how long it would take and that it would be necessary to bring your own lunch.
- The level of involvement in the study needs to be made clear (the number of visits to the CRF, how long participant would be participating etc)
- Participants weren't clear that taking part in the pilot Study meant they wouldn't be part of the main Study.
- The consent to contact form was very straight forward.
- Participants were generally happy with the length of time between completing the consent to contact form and receiving a phone call. A few participants did comment that the length of time could be shortened. One in particular mentioned that "I had almost forgotten about the Study when I received the phone call".

Route B (posters, adverts, emails)

- "The advert on 'MumsNet' didn't give much information. I had to email to find out more about the Study."
- "A friend saw an advert online and passed the email information on. This was originally seen on the ESRC website, and the friend followed the link to the UCL website".
- Participant heard about Study through online group of mums. Someone posted a link about the Study and participant looked for info online (participant remembers looking at the website, which had enough information), and then sent an email to NatCen to register interest.
- "I chose email to get in touch because it's easier."

Following the completion of a 'consent to contact' form or after registering interest in the Study participants received a telephone call to check eligibility, collect basic information, answer queries and make an appointment. Participants were generally happy with this process; felt that communication was very easy and that it was straight forward to book an appointment.

None of the P28s spoken to had initiated the visit to the clinic, spoken to the Telephone Unit themselves or directly consented before coming to the clinic. All P28 contact was initiated and organised by M28s. P28s were less engaged than M28s overall. Other comments included:

- It would be helpful to be able to fill out a form online or email details instead of giving them over the phone. This will also ensure details are more accurate (participant's name was spelt wrong at the clinic).
- Participants would have liked to have been told how long the visit would take in advance. Few participants recalled any material telling them how long it would last.
- P28s and M28s with children should have been offered weekend slots. Those with children commented that the weekday appointments were difficult to manage around older children's bedtime routines and also affected childcare arrangements.

- The Telephone Unit should be clear on all details of the Study. One participant asked where the Study was taking place and the telephone interviewer was unable to answer.
- The email address was appreciated; it was a really easy way of getting in touch.
- Preference was to receive information by email.

Before visiting the clinic participants generally discussed the Study with partners, family and friends. M28s mentioned that it was particularly important for them to have discussed the Study and obtained approval from their partner before attending/making an appointment as "it's their baby too".

19.3 Recruitment Materials

Participants received various materials to engage them in the Study and provide appropriate information. Documents received varied depending on the method of recruitment. Participants recruited via email were emailed a pdf of the Participant Information Sheet. A common theme was that documentation was not clear about the length of the appointment or what the key aims of the Study were (what hypotheses were being tested). A summary of comments made about each document are detailed below:

Postcard

- Only one participant recalled receiving the postcard. It hadn't been used to store their scan photo and they hadn't felt it was particularly memorable.

Bookmark (and teabag)

- Only one participant recalled receiving a bookmark and teabag. The participant only recalled the bookmark after being prompted about the teabag. The participant did use the teabag.
- "If the bookmark had been relevant to my baby or grabbed my attention more (more colourful) I may have noticed it more. I don't look at anything unless it's toy-related or something physical that can be used".

Participant Information Sheet

The Participant Information Sheet (PIS) was given, emailed or posted to any prospective participants. Initially NatCen were told to give participants seven days to read the PIS before phoning to book an appointment; this was later reduced to five days. If participants contacted NatCen directly to say they had read the PIS, an appointment could be made without further delay.

Feedback from participants suggests P28s were less engaged with the PIS, participants would have appreciated really clear Study aims and more information in preparation for the appointment (e.g. duration of the appointment and appropriate clothes to wear). Comments are summarised below:

- Despite being in the PIS, several participants didn't recall seeing anything about the length of time to allow for the appointment.

- Some participants noted that there were no pictures of fathers or anything to engage P28s in the Study. “It wasn’t clear that partners could also participate”. One P28 commented that “I didn’t pay much attention to it. I’m very busy at work so I didn’t really focus on it at all.”
- “A paragraph at the front of the leaflet containing a summary would have been helpful.”
- Participants were unclear what their involvement would be after the initial visit to the clinic (they weren’t clear it was a one-off pilot study). “The main Study leaflet should be clear about participation throughout the course of the Study.”
- “A study timetable of what would take place and when would be helpful.”
- “The leaflet was visual and attractive.”
- “The leaflet was very user friendly; it wasn’t heavy with too much information. It was very easy to navigate.”
- One participant felt the ethics should have been placed to the rear of the document. “The stuff about data being held securely etc. doesn't need to be at the top, it’s better to let people know what the study is about first. The legal stuff all sounds a bit ominous“.
- More information about what the different aspects of the Study actually involved and how to prepare would have been appreciated. For example knowing about the skinfold measurements so could dress appropriately for the measurement (M28), knowing about the digital photo of the eyes (M12), knowing about the urine sample (M12) and being informed in advance that they would be filmed so they could be prepared (M6, M12s)
    - “It would have been helpful if the urine test was mentioned somewhere, so I knew to bring an extra nappy. Also something about baby's clothing as they are undressed too.”
- The aims of the Study were not clear in the PIS, several participants didn’t understand what the bigger picture was. “There wasn’t a great understanding for what the Study is doing”. Several participants commented that an example of the hypothesis being tested, or what the data will be used for would be helpful.

Appointment letter

The appointment letter was posted and/or emailed to all participants who had booked an appointment. In addition all participants were sent an email/text reminder the working day before their appointment. Most participants felt there should have been more information about the length of the appointment, details on the location of the clinic could also be made clearer: Comments are summarised below:

- ”Perhaps a confirmation email/text of the appointment time the day before would also be helpful.”
- “The appointment letter should have contained more information about how long the appointment would take.”
- “The letter should have contained information about whether lunch would be provided and nearby facilities where lunch could be bought.”
- Several participants commented that it would have been helpful if the letter contained directions from all closest tube stations as well as details regarding

buggy accessibility from each. The letter only mentioned Euston square, not Warren Street or Euston. “The letter assumed you would be coming from Euston Square but this won’t be the case for all mums, I came from Warren Street”.

- Buggy accessibility at nearby tube stations is important. “The map wasn’t clear there was an underpass on Euston Road, this was inaccessible with a buggy and it made travel to the clinic difficult”. “It would have been helpful to include information about accessibility at local tube stops in the letter e.g. there are no lifts at Euston or Warren Street”.
- Some participants commented that the map and address were confusing. “The map was useful but it should have more clearly depicted that the entrance needed was round the back of Euston Road. If the address is typed into Google it takes you round the front of the building so it took a bit of working out.”
- “The address of the street was wrong.”
- Several participants commented that the letter was not clear about why participants had to bring their red book or other items along. They stated it was heavy to carry and then wasn’t used. “I wasn’t sure why I was asked to bring my pregnancy notes when they didn’t seem to be used or needed.” “I wasn’t sure why they wanted me to bring my glasses prescription when they were measuring my glasses anyway”.
- “The letter should be formatted so that the checklist of items to bring is easier to spot. It was on the reverse of the letter and so easy to miss.”
- The letter should make things really explicit “It said something about wearing loose clothing. I thought the dress I was wearing was quite loose but I was also wearing maternity tights which I was unable to remove for the BIA. If I had known I would have turned up in socks, they would have been a bit easier to take off for the BIA measurement”.

Pre-complete Booklet

All M6 and M12 participants were posted a self-completion questionnaire (of around 60 questions) to complete and bring when they attended their appointment.

- “Some of the response options were not clear, for example for the question “How often do you read to your baby?”. The options were “every day” or “every 2 to 6 days” this seemed like quite a large spectrum to cover.”
- “Some questions were oddly worded or it wasn’t clear what the question was asking”.
- “Some of the routing was odd or response options were limited, for example there were a series of questions where you were asked questions like “can your baby stand supported?”. It would have been useful to have a box to enable you to tick if your baby can walk, this would have eliminated all these questions.”
- “The questions about harming your baby were quite personal and may have raised some issues for some people. You had to be very honest with yourself.”

Other comments are noted below:

- A couple of participants commented that the pre-complete arrived after the appointment letter.

- There were a range of estimations of how long it took to complete (between 10 and 20 minutes).

19.4 Clinic Appointment

Location, travel and travel expenses

Participants were very positive about the location of the pilot clinic due to its central location and proximity to the antenatal ward. Participants generally felt it was appropriate to be reimbursed travel expenses and that it made participation more appealing:

- "It was at the same location as antenatal appointments which was convenient but it wouldn't have been feasible to attend following an antenatal appointment because of the length of time involved. It was accessible and easy to find".
- "I was pleased to receive travel expenses, it made participation more appealing".
- "The Study should fund the correct travel expenses as this would encourage more people to participate. Mums who don't use public transport or who live a bit further away may be discouraged from participating if they incur extra cost travelling."
- The provision of a taxi was commonly suggested for mum's who would be leaving the clinic late or those who are not used to taking public transport in London. "It's useful to have the option to get a cab home in the evening if need be".
- "Being reimbursed travel expenses was important; I would definitely expect them for the main Study".
- "I participated after work so travel expenses were covered but if had to travel into London on a non-work day I wouldn't have participated due to the cost".
- Several participants noted that better sign posting of the clinic within the hospital would have been appreciated.
- "It would be good if the study provided the correct travel expenses to encourage more people to participate."

Venue and facilities

Participants felt the Clinical Research Facility was a happy and warming environment but it was not suitable for children. The lack of provision of lunch or facilities to buy suitable refreshments for particularly long appointments was also noted:

- "It was a very happy warming environment, very clean. Staff were very helpful and polite."
- Two of the participants who were still breastfeeding noted that the clinic would benefit from having somewhere "nice and comfortable to breastfeed." "I had to breastfeed in a room with a chair and desk and it wasn't very comfortable."
- Two participants who were still breastfeeding were also concerned that they had been at the clinic the whole day and had to go without lunch as facilities to buy lunch weren't provided. "They had tea and coffee but they should have provided lunch or they should have mentioned that it was going to be the whole day so I could have brought my own lunch. I didn't know I wasn't going to get lunch and

I'm breast feeding. The whole day I ended up having only tea, coffee, biscuits and had only brought one snack for baby, that wasn't good."

- Baby changing facilities were not always seen as suitable; one participant was concerned that her child would roll off the hospital bed. "Baby changing was a problem. I had to change him on a patient bed and as he is quite mobile this was a difficult task!" However others were happy with the baby changing facilities ""I quite liked the venue, the changing facilities were good and the toilets were good."
- Toilet facilities were generally viewed positively. "It was good to have easy access to toilets (especially if pregnant)"; "The toilet facilities were great!". "The toilets were adequate and clean".
- M12, M6 and M28 participants would have liked to have known how long the appointment would take in advance so they could prepare for the whole day, bring enough food for themselves and babies and enough nappies (particularly given the urine collection which involves changing the nappy). The facilities were not felt to be adequate for the length of the appointment.
    - "I was offered water and tea. But no food. This was not an issue as I brought snacks but being pregnant it would have been good."
    - One M6 commented that food should have been provided "even if we had to pay for it".
    - The nature of the food provided was also commented upon. "Given the length of the study it would be a good idea to have some snacks and some hot drinks or maybe something with sugar." "I would have appreciated water when you arrive and fruit instead of biscuits, it didn't feel very healthy. When you're pregnant you need to be looking after yourself and eating good stuff".
- The kitchen facilities and provision of fresh whole milk were appreciated "I liked the fact there was a kitchen where I could boil water for the baby's food, and that there was fresh whole milk in the fridge." Participants also commented how nice it was to receive "hot drinks/waitress service" while they were participating.
- The venue was viewed by some as too clinical and unsuitable for children. Participants commonly mentioned the need for child minding/babysitting facilities or the provision of toys. Participants noted that questionnaires and adult measurements were difficult to complete with children present and there were concerns over the safety of unsupervised children within the clinical environment. Babies became bored and fractious when parents were occupied with CASI or measurements and would have benefited from there being something to entertain them.
    - "It was too clinical and some aspects were a health and safety risk."
    - "There were things in the room that baby was playing with that were not good, they should not have been in the room."
    - One participant commented that her 1 year old was trying to pull hospital equipment off the wall while she completed CASI and child minding facilities would have been appreciated. "If you are expecting participants to answer questions using mental arithmetic then you need someone to child mind so you are able to fully focus on the questions. My baby was trying to pull hospital equipment off the wall during the three minutes of mental arithmetic and it was a bit ridiculous."

- "The Venue was all very nice, but there were a few issues when you have an active one year old. All the rooms were very equipment-heavy and my baby liked to put his fingers into things which is not ideal when there's lots of hospital equipment. It could have done with a safe space for children to play, equipped with toys and things."
- "It would be good to have some toys for baby to play with if you're going to ask mum lots of questions. Baby became bored."
- "It would be nice to have somewhere for our little boy to play, we didn't really want to send him off to play in the hospital"
- One participant was concerned that there was "not enough hand gel in every room."

Waiting time, length of appointment and flow

Participants were asked how long they were in the clinic, whether they had to wait and if they had any comments on the length of the appointment overall or the flow.

- Most participants commented that the appointment was too long and they felt tired during or after the visit. The length should have been made clearer in advance so participants could plan their time. M28s found the visit tiring and long having been at work during the day.
  - "The flow needs to be kept quite fast paced".
  - "It felt like I was there for a really long time, I was a bit brain-dead by the end of it".
  - "After the first hour was thinking, 'I wonder how much more there is', but decided not to ask and just take it as it comes. I was a bit relived when I was told I was at the last station!"
  - "I did think this was a bit long for pregnant women (to go without eating anything or having a rest). Up to 2 hours would have been more manageable."
- One M28 commented that she had to rearrange childcare arrangements due to the unexpected length of the visit.
- "The length of the appointment meant it would not have been feasible to pop in after an antenatal appointment".
- Participants did not find waiting time to be a problem. "No real waiting involved between stations. Flow fine - thought it was good having the CAPI first, because that was quite easy, just being asked questions."
- If participants did have to wait they suggested they would have been happy to wait for a maximum of 5 minutes. "I didn't have to wait but if I did I would have waited a maximum of 5 to 10 minutes." Some participants had to wait due to technical issues with connectivity.
- Opinions were mixed on breaks. "Thought that the structure of the visit could be rethought -possibly include a break, or speed things up." Some participants would have appreciated more opportunities to use the bathroom (particularly M28s) whilst some participants felt they were happy to just get through the stations as quickly as possible. "I would have liked to be given the choice of having a break in between stations, I need the loo every 20 minutes!".

- M6s and M12s felt that timings should be worked around child nap and feeding times so that infants remain less tired and more alert (particularly for infant observations, the infant vision assessment and eye tracking). Infant observations should have been done at the beginning of the day as baby became tired. “The observations could be done earlier in the appointment when the child is happier and more alert than towards the end when baby’s starting to get fed up”.
- Participants felt positive about moving to different stations and reported that it kept things interesting although the order of stations could have been made clearer. Participants weren’t always sure what station they needed to go to next.

Reception

Participants were asked about individual stations that they visited including Reception. Participants felt the Reception staff were very friendly, welcoming and helpful. However they would have appreciated an overview of what was to follow:

- Participants commented that at the beginning they would have liked to have been provided with an overview of each station and how long each one would take so they had a clear picture. .
- “At the beginning they should clearly explain what they’re doing and what the visit will involve. “Maybe the receptionist could do a spiel saying ‘you’ll be going to x number of stations and this is what the 3 hours will entail’”

Stations: CAPI (including consent)

The first station participants visited in the clinic was CAPI. At this station participants completed a consent form and answered a face to face questionnaire. Feedback about the CAPI station is summarised below:

- Consent information was clearly explained and participants understood what they were consenting to. Some technical issues were encountered with the consent tablet due to Wi-Fi issues.
    - “Consents procedure was fine.”
    - “I had some questions about data protection which were fully answered.”
    - “The consent process was made very clear.”
    - “Problem printing the consent form, so I completed the electronic one then a paper version too. Clearly explained, and understood what I was consenting to.”
    - “There were technical problems with the tablet consent and printer, although it was fine – just the clinic staff who had to deal with it.”
- Participants commented that additional information on certain consent topics would be appreciated:
    - “I wanted to ask what the statement about giving permission for individuals from regulatory authorities to have access to Life Study data meant”
    - One participant also commented that more information on how the data will be linked to medical records would be useful as her child has chronic health conditions.

- Several participants said it would have been helpful to know about the topics of questions in advance (particularly the finance questions) so they could prepare. Some of the information is not easily recalled.
    - "It would be useful to be told what would be asked about my financial situation in advance so that I could arrive prepared as I did not know."
    - "There appeared to be a lot of emphasis on financial background but not much emphasis on health or education. I wasn't sure why there was so much emphasis on finance but not other areas."
- Some participants felt the finance questions could be quite intrusive and wondered why these were asked face to face and not as self-completion
    - "Overall fine. Income questions were a bit difficult to answer (and some people might find them sensitive)."
    - "I didn't find the questions intrusive but could imagine that some people might."
    - "The income section is far too detailed …. and why face to face for income questions? I would have preferred the anonymity of self completion".
    - "It would be preferable to answer these on a computer not to a person as it feels sensitive."
- Questions on abortion and miscarriage were also found to be intrusive and oddly placed by some:
    - "It didn't seem appropriate that questions about miscarriage, abortion and still births were asked by a man and by someone who was not a medic. Questions of this nature also need to be delivered in an appropriate manner (non-smiley)".
    - "I found it peculiar that one of the first questions was about abortion. It would be hard for certain interviewees to talk about this and it should be asked later on in the interview or in the self completion questionnaire."
    - The routing for questions on still birth/miscarriage "seemed odd". Participant was asked if she had been pregnant before and when responded "no" was asked about pregnancy and still births.

Other more general comments are noted below:

- "The questions about medical conditions were quite difficult to answer because my baby has had a lot of medical conditions. These questions did not follow chronologically and it felt like they were jumping about a bit".
- "I would have thought there'd be more in there on health as it's a health study."

Stations: CASI (ease of use)

The Pilot entailed participants completing two sets of CASI (self completion) questionnaires on a touch screen monitor. Participants were asked about the ease of use of the touch screen monitor:

- Most participants found the touch screen easy to use. However when inputting numbers it was unclear whether to use the touch screen or the keyboard.

- "The touch screen was ok but there was a lot of superfluous pressing of the 'NEXT' button. In some instances the CASI could have launched straight into the questions."
- "It should be made clear that to navigate through the CASI you can click on the item twice."
- "I can see why measurements have to be done in clinic but felt the questionnaires could have been done at home via a web questionnaire or self completion booklet."
- Several participants noted that they were "unclear what the distinction between the two computer bits was".
- Some participants who had children accompanying them felt that childcare when completing the CASI would have been helpful.
    - "If I'm expected to answer questions about mental arithmetic then childcare should be provided".
    - "I had my partner with me but I think if I was on my own the questionnaires with the touch screen would have been a bit difficult if the baby got a bit fed up or difficult".
- A number of participants also commented that the CASI booth did not allow enough privacy.
    - "Questions asked are quite personal so would appreciate personal space."
    - "Perhaps introduce booths or ensure that the participant's back is facing the wall."
- Other participants commented that answering personal or sensitive questions honestly may have been difficult on CASI as they felt they were being watched.

Stations: CASI (questions)

Participants were asked about the content of the CASI. Participants felt the content was quite long and suggested having a questionnaire that could be completed on the web at home to shorten the overall time spent in the clinic. Participants were unclear as to the purpose of a lot of the questions. There were a number of questions which stood out as being odd or difficult to answer:

- There were some inconsistencies in the questions for example at one point it stated "I'm now going to ask you some questions about the birth" but nothing followed on from this.
- P28s enjoyed the IQ test. One commented that they would have liked the results.
- The question about cosmetics was not clearly defined. It was hard for participants to recall all the products used, 'every woman uses about 10 make up products'. The question asking 'where you apply cream' did not provide clear response categories. Several participants wanted to select 'face' but the only option was 'upper body'. Two participants admitted to cheating on this question to avoid having to input every single product used.
- There were a couple of questions about detergent use and make up. One participant noted that she uses detergent and make up but only uses natural products so there should be somewhere where you can record that.

- "The question about vitamin D was very odd, there wasn't any element of seasonality to it for example "I cover myself because it's cold" or "I use sunscreen to protect myself from the sun. It seemed that the only reason you might cover yourself was for religious reasons".
- The questions were very British-orientated. "Despite having lived in Britain for 9 years there were a couple of terms used where I wasn't clear on the subtlety of their meaning."
- There were questions about relationships which asked how close you were to your family and how often you see them. One participant commented that she has a wonderful relationship with her family but only sees them twice a year as they live very far away. The questions didn't seem to allow for this response.
- Several participants commented on the 'Top 5 travel destinations question' – some noted that these questions took too long to fill out and the question was a bit weird.
    - "Another weird question was about the place most often visited at weekends / weekdays. Weekdays, if working then this is probably ok, but at weekends - it is difficult to say… and difficult to provide an address… Too long if completed properly."
    - "Also found the 'where do spend most time at weekends' difficult to answer – just varies too much to say. "
- M28. "It was good to be asked questions about bonding with the baby because I hadn't really thought about it before. I've been doing this since the visit".
- Happiness with weight question – participant noted she is not happy with her weight and is trying to address it however the CASI didn't seem to allow for this response.
- "I thought some questions were too personal. I wanted to know why they wanted to know if mum covered the head of baby or if mum and her partner shout at each other. I didn't understand why they had to ask that or what it has to do with the study perhaps they wanted to see what sort of environment the baby lives in."
- "There was one about whether baby had been fed from a bottle. I wasn't sure if it meant any kind of bottle or meant water bottles, juice bottles, not including milk bottles. I had to call someone over to clarify what it meant."

Stations: Infant anthropometry

Participants were also asked about their experience of other measurements and assessments in the clinic including infant anthropometry. Participants generally had less to say about the other stations. A common response was "it was fine". For infant anthropometry participants noted that babies were often tired by the time they got to this station and so became quite fractious. Participants were generally more uncomfortable with the skinfold measurement being taken on baby. Participants would have appreciated receiving results of the measurements. Feedback is noted below:

- "I felt a bit funny about the skinfold measurement on baby but the interviewer was great and really put me at ease by demonstrating on my arm first".

- “Measurements took a long time due to being repeated 2 or 3 times, baby was becoming quite fractious.”
- Participants were least happy with the skinfold thickness measurement being taken on baby. “I felt a bit funny about the skinfold thickness measurement”.
- Participant didn’t receive information in the pamphlet; all the information was from the person taking the measurement. “They were very clear. For every measurement they checked it was ok and obtained consent.”
- “Not too bad – all fine really. Baby was starting to get tired, so he was a bit grumpy, but generally fine.”
- Participants would have liked to have had results / the chance to record results for the baby. M12 “The main thing is to be given the feedback, if no feedback is given I don’t think I want to do it because I think, what’s the point for me”.

Stations: Adult anthropometry

Common themes about adult anthropometry were:

- All of the participants in the follow up commented that they would have liked to have received feedback telling them what the measurements meant.
- “The measurements were very clearly explained.”
- “The lady was great at putting me at ease”
- M12 “The adult measurements were challenging as my baby became distressed.”
- Interviewers should be prepared to explain the measurements to participants because they’ll be curious, e.g. “why’s my BMI this while I’m pregnant, what does that mean? What should it be?”

Stations: Vision

Part of the Pilot visit involved an vision assessment encompassing an assessment using a PlusoptiX device, a test of stereovision, a digital photo and a reading of the participant’s glasses (if they wore them). A vision assessment was conducted on all M28’s, P28’s and M12s. Comments were:

- “There was no vision assessment as my baby had fallen asleep.”
- “The eye test was done first without asking about my eye sight. This seemed a bit funny because I’ve had my eyes lasered but they never asked about it.”
- “Fine. Computer didn’t work initially, so the operator had to go and sort it out – all handled very professionally.”
- “Why ask for a copy of my prescription if going to measure glasses for prescription?”
- “Surprised how quickly this was done. One of the questions on the vision test – family eye problems wasn’t clear enough. I talked about grandfather’s glaucoma, but didn’t realise wanted short /long sightedness as well so had to go back and change answers. Would have been good to have had example when question asked. “

Stations: 6-month Child Observations

All M6 participants were asked to take part in a number of child development observations which were filmed. Feedback for this task is limited as it was only possible to contact two of the four M6s for a feedback interview.

- Participants felt awkward in front of the camera and it didn't feel very natural. One participant commented that "I felt a little bit put on the spot, it's hard to act natural when you have two cameras in your face".
- The participant materials should mention that they will be filmed so that they are prepared for what to expect. (This is in the PIS but hadn't always been noticed).
- Found the mother's still face exercise really difficult.

Stations: 12-month Child Observations

All M12s were asked to take part in a number of child development observations which were filmed. Four of the five M12s were interviewed about their experience. Three of those interviewed raised concerns of the relevance of the posters to the age of the child. Other comments are noted below:

- Several infants were sleepy and not very alert for this observation. Comments were made about the importance of conducting the observations after the infant's nap when the child is most awake and alert. "This took place when my baby was an hour overdue his nap so he was knackered."
- Several parents noted that posters used were not relevant to the age of the child and would not have much appeal to a 1 year old. "It would have been better if the pictures were of characters that are on television these days like Peppa Pig or Waybuloo. Most of the posters used in the room wouldn't appeal to a 1 year old." "The posters were not relevant to the age of my baby, he would not have known who any of the characters were apart from peppa pig (as his brother watches peppa pig)".
- It was not understood why such a small gesture (short armed point) was used in the joint attention task. "The gesture in the joint attention task could have been made bigger and more obvious to elicit more of a response."

Stations: Eye Tracking

Infants of M6 and M12 participants were asked to take part in the Eye Tracking task. Nearly all participants commented how much they enjoyed this station and how interesting they found it. Other comments are noted below:

- "The eye tracking was quite long which meant it was easy for child to lose concentration."
- "I'm not clear why some of the images in eye tracking were pixilated and I would have been interested to know."
- "It would have been nice to receive feedback".
- "Baby loved it!"

- “I really enjoyed the eye tracking. It was explained really well by the interviewers and should definitely be used in the main study.”
- “Baby eye tracker was great. Baby was sleepy, so it wasn’t ideal, but it was really interesting watching him.”

Bio Samples: Urine

All infants were eligible for urine collection. Of those interviewed few had successfully managed to collect any urine for varying reasons. Other comments/themes about the urine collection follow:

- Was happy with baby providing a urine sample but didn’t really understand why they needed it.
- “Nappy was dry so could not provide a sample”.
- “They didn’t get much urine, only about two drops.”
- “The interviewer collected the urine from the other cotton wool ball, so no real comments, although looked like it was slightly more difficult than the bag collection she’d done before. One of the cotton wool balls moved out of position so didn’t collect any urine. It might be better to use a square cotton wool pad. That would be easier to position/more likely to stay in position.”
- “Urine test didn't work as the baby pooed, so unable to comment.”

Bio Samples: Saliva

Participants were generally happy for their baby to provide a saliva sample, however those who participated felt it took quite a long time. Comments and themes about the saliva collection are noted below:

- Saliva collection took a very long time.
- One participant commented that their baby couldn’t do the saliva collection as they were tired and had fallen asleep; “it was a very long day.”
- Some participants commented that they would have liked the saliva collection to be quicker and noted that if the baby had become upset they would have stopped it right away. “The saliva sample was just gross. It took quite a long time, it would have been good to use something bigger for the collection that might have been quicker. My baby dribbles quite a lot but even so it took quite a long time.”
- “It didn’t seem like the easiest thing to do. Because baby is not allowed to eat there is no saliva produced which made it difficult”.
- “Could this be done while mum is doing another test to save time?”

Accelerometry

All M12 participants were fitted with an accelerometer and all were worn for the full duration. Feedback on accelerometers was limited however participants were generally happy with wearing them.

- “It’s quite itchy to wear. I would not continue to wear if it became really itchy.”
- “I didn’t understand the purpose of wearing it.”
- “It didn’t fit all that well, it needed an extra hole.”

- "No problems. I felt that I should go out and do some exercise, so that it looks like I'm active"

19.5 Post Clinic

GP letter and Thank you letter

On leaving the clinic participants were provided with two documents in their participant packs which they were encouraged to take away with them and keep; a GP letter and a thank you letter. There was no detailed explanation given about why we were providing a GP letter. For the main stage, where the participant is potentially enrolling their unborn child in a cohort study, it may be more relevant for their GP to be aware of this than for a one-off pilot.

Only one of the participants interviewed had used the GP letter whilst other participants had been confused as to the purpose of it. Several participants did not remember receiving the thank you letter.

- "I didn't understand its purpose for the pilot."
- "I didn't see the point in the GP letter; I could understand its use for the main study if they wanted to access baby's medical records but was a bit confused about the point of it for the pilot."
- "I tried to give my GP letter to my nurse but she did not want it."
- "I didn't realise it was in the pack, perhaps it should be posted out afterward" (thank you letter)

Feelings on leaving the clinic

Participants were asked about their thoughts and feelings immediately after leaving the clinic. Upon leaving the clinic feelings were mixed. Participants felt positive about helping out but tired. Some participants also noted disappointment at not being part of the main Study (but also relief) due to the length of the visit. Several participants mentioned that following the visit they were deterred from encouraging family and friends to take part (who had previously been interested) due to the time commitment involved. Expectations, key comments and common themes are noted below:

- "It took a very long time and I felt very tired. Baby had to have nap a lot later than usual."
- "I was happy with all the measurements but two hours seemed like a long time to give up."
- "Felt positive about helping out."
- "I was disappointed that I wouldn't be able to be part of the main stage."
- "I didn't feel great that a lot of measurements had been done and no feedback would be provided."
- "Was not happy that had been at the clinic for a very long time and had not been provided with a proper meal/ food while breast feeding."
- "I expected the visit to be much shorter."

- “It didn’t match the expectation as I wasn’t aware that a photo of the eyes would be needed.”
- “I didn’t expect to be video recorded.”
- “The experience was more positive than I thought as the staff were so appreciative”.
- “I had thought that would be involved in the main Study so there was an element of disappointment that I wouldn’t be in the main Study but also relief because it is time consuming.”
- “I was quite open-minded in terms of expectations. I thought it would be quite clinical but found everyone there to be very friendly and it was very relaxed, it wasn’t “doctor like”. It made us all feel relaxed and it made baby relaxed.
- “I had told my husband I was participating and that partners were welcome but afterward I told him “I don’t think you’re going to do it because it’s two hours long”. I would have suggested the Study to my sister in law and other people but given the time commitment I wouldn’t bring it up, definitely”.
- “I posted on facebook, another friend had also been to the clinic and we both commented that it was a long time and the babies were knackered.”

Whether participants had changed their behaviour since visiting the clinic

Participants were asked whether they had changed their behaviour as a result of visiting the clinic. A couple of participants had done so:

- The mother’s still face exercise made one participant more aware of her baby’s reaction to not being able to see mum.
- One expectant mum said that some of the questions had prompted her to start talking to her unborn baby following the visit.
- One mother commented that she has started to look at her child’s development in slightly different way and has more awareness.

Would participants come back for another visit (and if not, why not)?

Finally participants were interviewed about their intentions should they be invited back for another visit. Common motivators for a return visit were the introduction of a financial incentive, feedback on measurements (particularly child measurements), the provision of childcare and a shortened visit. Feelings overall were generally positive and interviewees commended the positivity of the NatCen team.

- “I’m more interested in the child development stuff so I would come back if was more related to the child.”
- “It would depend on the length of the visit.”
- “I would come back if received the correct information in advance such as how long the study would take and whether it is necessary to bring your own lunch.”
- “I would come back if there was some sort of incentive or feedback.” This was a common theme raised by participants.

- P28: “I would do it again, a financial incentive would sway it. If there was childcare provided this would also make it a lot easier.”
- “I discussed the visit with my husband. The hours are difficult for him to get there, he would have been happy to come on a Saturday or Sunday work wise but only if he was being paid £40 or £50”.
- “I would be happy to go again, but I think more thought should be given to what children of 12 months need, and make sure that’s provided. It should either be a long day with breaks for play and naps, or a shorter visit, so kids don’t get bored and tired.”
- “If I had another baby I would definitely like to be part of the main study as it was really interesting and I would have loved to have seen the results of the study”
- “I’d be happy to come back I found it quite an interesting experience”.
- “The manner of everybody at the clinic from the reception all the way through to the face to face, they were brilliant, they were really really brilliant”.
- Everybody in the clinic was really friendly and polite, they made it as easy and gentle for the little one as they could which was really good.
- “The staff were amazing, they were very understanding and very gentle and that’s really important for the main Study. If the staff are the same in the main Study everybody would have a really positive experience.”
- “You have a really friendly team. The positivity and energy is really good. If you keep the team upbeat it will keep people going back”.

20 Interviewer Feedback

20.1 Introduction

In the last week at the CRF interviewers were asked to complete a short debrief questionnaire about their experiences working in the Life Study clinic. This is included in the appendices to this report. Ideally a face to face debriefing of all the interviewers together would have taken place but was not possible as interviewer availability was limited and the time available for report and data delivery also very condensed. As well as using information from these questionnaires in this section, we have also used comments that interviewers made in the clinic on the daily appointment sheet.

Of the 21 interviewers who worked in the clinic 16 completed the paper questionnaire. Complete questionnaires were handed in anonymously. Topics covered in the questionnaire were:

- Briefings
- Venue (CRF)
- Length of appointment and flow
- Documents
- CAPI questionnaire
- CASI questionnaire

- Stations
- Equipment

20.2 Briefings

Four separate interviewer briefing days took place. The first of these was a theory day off site designed to provide interviewers with an overview of the Life Study and the visit structure. The remaining briefing days were clinic based briefings where interviewers were walked through SOPs and provided with the opportunity to practice various measurements and protocols. For clinic based briefing days interviewers were split into groups therefore not all interviewers were trained on all measurements. The key groups were:

- Vision, Eye Tracking, Child Observations
- Anthropometry
- Reception, CASI and CAPI

All interviewers felt that more time should have been provided for training and hands on practise in the CRF to gain confidence “there was a lot to learn in a short space of time”. Interviewers held mixed opinions about the usefulness of the theory day. Some interviewers found it helpful and informative however some were confused until they were able to visit the clinic and have a walk around.

The impact of slow and intermittent WiFi connectivity at the CRF was that interviewers struggled with getting to grips with the unfamiliar measurement devices and felt that these IT issues impinged on time which should have been spent learning. Interviewers found the clinic based briefings very long days and it was tiring having to stand for long periods.

Interviewers briefed in anthropometry felt a lot more content with the clinic-based briefings than those trained in vision, eye tracking and child observations. Interviewers trained in adult and child anthropometry felt there had been plenty of opportunity to practice and there was always plenty of support provided in the clinic. Conversely, interviewers trained in vision, eye tracking and child observations felt overwhelmed by the amount there was to learn in briefings. It was suggested that it would have been helpful to have a specified training room containing equipment where they could have practiced on weekdays to refresh their skills.

20.3 Venue

The venue caused a number of problems for the pilot, which will not be experienced at the main stage as we understand that the main stage venues will be solely used for Life Study and will be laid out precisely as required.

We feel it is worth mentioning some of the issues that interviewers raised, as it does reiterate the fact that the venue had an impact on how well they were able to do the work required of them. It also highlights practical issues that may need to be considered for the main stage venue.

The pilot study took place at the University College Hospital (UCLH) Clinical Research Facility which is which is an operational clinical research facility running a large number of oncology clinics during the week treating patients of UCLH. NatCen had access to rooms for adult measures after 3pm on weekdays and rooms for infant measurements at weekends. The nature of room availability meant that at the beginning and end of each clinic working day (or weekend) all equipment had be set up and closed down and stored in a separate area within UCLH.

Interviewers felt strongly that the venue was not suitable for the needs of the pilot study and that the pilot should have taken place in a dedicated venue. Setting up and packing away rooms each day was very difficult and time consuming and it heightened the risk for items to go missing or equipment to become damaged. The poor WifFi connection was also repeatedly noted as an issue. Interviewers were very concerned about the health and safety hazards in moving very heavy equipment. Given that setting up, closing down, storage and collection of items was necessary on a daily basis, better provision should have been made:

- "Cages were problematic and the storage and collection of them was difficult on a day to day basis".
- "Not all boxes were suitable due to the nature of having to pack and unpack on a day to day basis, lists of contents were not always visible or accurate. Clear plastic boxes worked much better. Pack-up at the end of clinic where interviewers are all involved in cages can be a little disorganised."
- "The lack of cages made things difficult initially."
- "There was excessive manual handling."

Interviewers expressed some concerns about the suitability of holding the study in a clinical environment and in particular conducting a study involving young children in a facility where patients are being treated for cancer. Other comments made are detailed below:

- "It's impossible to clear rooms to conduct the study in the optimal space."
- "There were several people and things behind the Reception desk which made things difficult."
- "Space for sleeping babies, breastfeeding or a play area for older children was lacking."
- "Some of the stations could have been a potential cause for concern due to obstacles in the way/sharps boxes being left open. There were too many 'other' distractions in the room."
- "Difficult working in an environment where patients were coming for treatment for serious illness."
- "An area to occupy children would be useful. When a mother is on the BIA machine and the child happens to lean on it it skews the reading."
- "Heating appeared to be turned off on a Sunday so was quite cold for the participants in anthropometry."
- "Staff lovely, friendly and very accommodating."
- "Great layout and structure of the clinic."

- "Central location easy to find for staff and participants."
- "Reception, CAPI and anthropometry rooms were adequate."
- "The three CASI stations were spread out and not easy to man. Would prefer them to be closer together and separated by booths."
- "Limited access to the staff room, no adequate space for personal items."
- "Venue with parking (especially for respondents with small children) would have been preferable."

20.4 Length of appointment and flow

For the main stage there will be a different staffing model, so the comments here relate specifically to the pilot. Again, we feel it is worth including these as some of the comments may help to inform decisions at a later stage.

Participants attending the clinic were asked to attend various stations in a particular order or "flow". Interviewers were asked whether they had any comments on the flow of the clinic, waiting time or the length of the clinic appointment overall.

All interviewers felt that the appointment length was excessively long and tiring for participants (particularly those with small children). Interviewers noted that participants had often not been made aware of the length of the appointment upon recruitment. The length of the appointment was too long to go without a proper break or refreshments.

Interviewers felt that 'free flow' worked better in the clinic to allow for 'bottlenecks'. The flow should be flexible to allow for respondents needs (e.g. if infant is due a nap or a feed). Other key comments provided by interviewers were:

Length of appointment:

- "3 hours is quite a long time to spend in the clinic when a participant has been at work all day"
- "6 and 12 month babies became restless after 2 hours."
- "CASI is too long."
- "Anthropometry is quite long."
- "The visits were far too long especially for participants with small children. Most children who came through had to have a nap at some point (which made the visit even longer). Participants commented that tasks which required the child to be alert would have been better at the start of the visit when the child is fresh."
- "Some of the participants said that the length of the appointment was much longer than they had been told."
- "The average time spent with mother and baby was 4 to 5 hours, suggest splitting the visit into two."
- "The overall length seemed far too long. This also meant a lot of down time for members of the team when there were insufficient participants."

- "The appointment times are very long, especially for mothers who have brought children along with them."
- "Too long without a proper break and refreshments or incentive. These elements will need to be built in."
- "The appointment was too long for the general public. The participants were more understanding as most of them worked in medicine or research."

Flow:

- "Flowed fairly well- 'bottlenecks' at times but not much of a problem."
- "Even with 3 participants there needed to be alterations to the flow to avoid bottlenecks."
- "There was a good flow of participants, the only hiccups occurred where babies needed to be fed or have a nap. Some mothers took a long time with their CASIs because they had to watch their toddlers at the same time."
- "The flow worked well but it should be possible to alter the flow if bottle necks occur."
- "Not enough thought given to be able to juggle the flow."
- "The ability to change the flow depending on the situation was good and met the respondent's needs better."
- "A lot of time was wasted having to set up and pack away; the flow could have been improved if this did not have to be factored in."

20.5 Documents

Interviewers were asked for comments and feedback on the suitability of the training materials, protocols and appointment sheets. Interviewers felt that crib sheets were a good addition to protocols and labelled and colour coded IT/equipment sheets aided set up. A cohesive set of protocols filed in one place would have been appreciated by interviewers due to the amount of paper work. Interviewers also noted difficulties encountered using vision chart and flow diagrams. Other comments are noted below:

- "Protocols were very clear."
- "The documentation was very good. It would have been better to be given a folder with everything in at the start rather than ad-hoc distribution."
- "Good but took about half a day to fall into place."
- "Too many bits of paper."
- "Protocols would be better kept all in one place in a booklet so everyone had everything."
- "Crib sheets worked well and were appreciated in addition to the SOPs"
- "Photographic detail of how equipment joins together is essential."
- "The IT instructions for setting up were appreciated and the colour coding worked. The colour coding could have been improved if there were numbers on the coloured stickers which relate to the instructions and identify each individual part

of the kit. Replacement stickers would have been helpful to ensure each piece of kit remains correctly labelled."

- "Daily Appointment Sheets worked well, good that clinic supervisor had one so could work out interviewer break times. It would be helpful to synchronise watches at the start of the clinic so that times do not differ for individual stations."
- "Daily Appointment Sheets could have been designed a bit better, there should be space to log two CASIs."
- "The laminated vision chart needs rewording as it does not relate directly to the flow charts and is hard to follow."
- "In vision the flow charts are not study specific which made them confusing."

20.6 Stations

Interviewers were asked if they had any comments or feedback about any of the stations in the clinic. Key comments and themes are summarised below:

Overall

- "It would have been better if the stations remained for the duration once set up."
- "Useful to have someone around to help with cups of tea/biscuits and to keep the participants happy."
- "Wireless issues."

Reception

- "A little cluttered behind the desk. Initially the printer was packed and unpacked on a daily basis, this was too heavy and provision should have been made for this."
- "Interviewers gathering in reception as a meeting place can be a little off putting for participant."

CAPI

Interviewers were asked to provide feedback on CAPI questionnaire length or content.

Questions which particularly stood out were those on miscarriage and still birth which interviewers felt should be more gently asked:

- Needs an introduction to each section especially the sensitive ones."
- "Sensitive questions could have been asked more gently."
- "When asking about previous pregnancies there should be an interviewer note to warn of the sensitive nature of the next couple of questions."

Interviewers felt that the CAPI questionnaire length was suitable:

- “Length and questions ok. The show cards need to be labelled and ordered so that they better relate to the Blaise questions; this would shorten the length of time spent on some of the questions.”
- “Good length, just enough questions.”

Other comments are noted below:

- “Having a good IT connection was important for ensuring that the tablet works efficiently and that the consent form is printed without delays.”
- “Consents printer should be set to default. The printer automatically reset itself which meant this process took a lot longer than it should have.”
- “Content was fine but wondered if this could be administered in another way to cut back on time within the clinic e.g. face to face interview at home or an online form that can be pre-filled.”

CASI

Interviewers were asked to provide feedback on CASI questionnaire length or content. The questionnaire was felt to be too long and interviewers suspected that some participants may have skipped through and not fully answered questions to get to the end:

- “Participants may have skipped through CASI 2 maybe not fully answering questions.”
- Too many questions and too long.”
- “Takes a varied length of time depending on how thoroughly respondents said they would like to complete this section. Both CASI components are quite long and quite detailed. Some participants commented that they left some sections incomplete as they did not have the information with them.”
- “The purpose of the questionnaire was unclear and it seemed like the participant was asked everything. This made it difficult for the participant to complete. Far too many questions were asked than were needed and it took far longer to complete than was necessary.”

Privacy of questionnaire completion was also flagged as an issue:

- “Privacy was an issue; the large screen could be seen some distance away.”
- “Participant commented that a more private area was needed for CASI completion.”

Interviewers also recalled the cosmetic and toiletries questions being rather unusual:

- “Some bizarre questions especially about cosmetics/toiletries. Not enough options were provided to choose from.
- “Many participants commented on the make up question which asks where on your body you wear it.”

One interviewer recommended that the CASI could perhaps be completed at another time at home “Content was fine but perhaps better to do at another time. This element doesn’t really need to be done in a clinic setting.”

The format of the questionnaire also received feedback:

- "The percentage bar at the top was worrying some people as the questionnaire would quite often end long before reaching 100%."

Vision

Interviewers fed back on their experiences of working on Vision. At this station interviewers administered an eye assessment encompassing a measurement of the alignment of the eyes, a digital photo of the eyes, a test of stereovision and a glasses assessment.

- "Great station to work on, couldn't fault it. "
- "Placing USBs in envelopes with barcodes was fiddly."

Eye Tracking

For all M6 and M12 infants interviewers administered an eye tracking assessment. Key concerns raised were surrounding the set up and close down of complex equipment.

- "Takes a lot of time, energy and strength to set up this kit. Ideally this kit would not require repeated set up. Once operators know the process for calibration this computer program works well."
- "The objects which made noises to attract the baby's attention varied in their effectiveness, some of the noises were not loud enough."
- "Too much IT set up to keep setting up and closing down."

Child Anthropometry

All M6 and M12 (infant) participants attended a station where they had their head circumference, weight, mid upper arm circumference, skin fold thickness (triceps and subscapular) and infant length taken. If consent had been provided a urine sample was also collected.

- "This was the second to last station at the weekend so the time the infant arrived they were very restless and it was very difficult to take all the measurements, particularly skin folds."
- "This station needed two people as someone needed to distract the child while the mother was being measured."

Adult Anthropometry

M28, P28 and M12 (adult) participants had various physical measurements taken including: waist circumference, weight, Bio Impedance Analysis, sitting height, height, and skin fold thickness (triceps and subscapular). M12 adult and child measurements were completed at the same time.

- "The M28 had problems being weighed; this happened a number of times and may be due to foetal movement."
- "Took a while to measure both mother and child."

20.7 Equipment

The Life Study pilot incorporated several new pieces of complex equipment. Interviewers were asked about the usability and suitability of the equipment provided for data capture in the pilot. Opinions on the usability of the equipment were mixed however interviewers were in agreement that setting up and packing away may have damaged equipment. Other themes and comments are summarised below:

- "All the equipment used captured the data that was required very well."
- "Problems with IT and communication at each station."
- "The rooms and free space within the rooms was the issue not the equipment."
- "IT problems were resolved by interviewers turning off the equipment and starting it up again but this required additional time."
- "Packing and unpacking may not be good for the equipment. The weight of the equipment and boxes was not taken into account and no cages or trolleys were provided for the first week. When cages were provided no smaller trolleys were provided to move boxes. This raised heath and safety issues as the ages and health of the team were not taken into account."

20.8 Comments and Suggestions

Interviewers were asked of any comments, suggestions or recommendations they thought would be helpful for the main study.

Interviewers felt frustrated that they were limited in working with participants due to the late arrangement of research passports. In future this should be planned for well in advance.

- "Lack of respondents and research passports hindered the pilot in its early stages."
- "OH clearance should have been done well in advance to avoid the situation where those who had clearance had to do the work of 2 or 3 interviewers at the same time at no extra pay."
- "Would have been better to arrange research passports before interviewers started working in the clinic."
- "Lack of research passport clearance has hindered quality of interviewer engagement and opportunity to collect data."
- "Due to the delay in the research passports I was not able to do adult anthropometry despite receiving training as others had become more 'expert' in this area through being able to administer measurements on 'real' participants."
- Travelled to London for vaccination but not necessary, this could have been discussed with phone call first.

Several interviewers noted that in a main study it would be useful to have a crèche facility or toys:

- "The study was a significant time commitment for participants and their family. It appeared that they found it tiring and did not have enough food with them to keep

their energy levels constant. Provision of suitable refreshments would assist in giving adult respondents the energy they need to fully participate in every station."

- "It would have been useful to have a crèche."
- "Toys for children to be kept amused or a crèche area would be helpful."

Other comments or suggestions made by interviewers are noted below:

- "Most participants were professional/educated people. In the main stage if an incentive was offered it may encourage a better response rate as well as participants from all social/economic sectors."
- "Enjoyed working on the project but travel time was 2 hours plus and this was difficult on Sundays in particular."
- "DVDs would be helpful to gain better tuition on the VETO/Anthropometry tasks."
- "Dedicated staff needed to work in blocks at a time not 1 or 2 days a week."
- "Lack of respondent recruitment has hindered testing of processes and data quality."
- "A longer preparation time would have been helpful"
- "It is a really interesting study; in a dedicated facility it would no doubt prove a great success!"
- "Great team to work with!"
- "Thoroughly enjoyed working on this project, the researchers were always very very helpful."

21 Data outputs

21.1 Summary of data outputs

A summary of final Pilot data outputs, including brief description, format and file sizes, can be found in Appendix A.

21.2 Data delivery

An interim dataset containing data for 37 participants was provided on 27 November. Final Pilot data delivery to UCL is timetabled for 30 December.

A secure ftp server was set up to enable secure data transfer between NatCen and UCL during the Pilot. Final Pilot data will be placed on the FTP server for download.

As part of the data delivery requirement all participant identifiable data has been removed before submitting the data.

21.3 Dashboard reports

A daily 'dashboard' report was made available via the secure ftp server. The report contained counts and timings for the clinic measures. A copy of the final report is in Table 9.2 and Table 9.3.

21.4 Data processing

21.4.1 Coding and editing

CAI questionnaire data

In order to systematically review the Pilot data and make informed decisions on questionnaire content for the main stage, it was recommended that the CAI data (consisting of CAPI and CASI, including administrative data for measurements) was not heavily edited. Minimal processing of the data has been carried out, with data cleaning mainly involving renaming of administrative variables and variable labels.

It was requested that all participant identifiable variables were removed from the dataset, such as name, date of birth, address, telephone numbers and email address. There are additional variables that were specified as part of the questionnaire development by UCL that could be disclosive, including

- Most visited locations, including reason for visit, full address
- Names and addresses of childcare providers.

These variables have also been removed from the final dataset.

SIC and SOC coding

SIC and SOC have been coded to four digits. However two digit codes will be added to the final dataset to ensure that participants remain non-identifiable to UCL.

Pre-complete keying

It was expected that around 25 M6 and 25 M12 pre-complete questionnaires would be returned to NatCen for data processing. NatCen therefore developed a data entry system to enable keying of the questionnaires.

In total, four M6 and five M12 questionnaires were received for processing. In line with NatCen's quality control processes, all nine pre-complete questionnaires have been double-keyed and verified to ensure consistency and accuracy of data entry. The provision of unedited data will allow for review the pre-complete content and understand the level of misunderstanding of the questions.

Accelerometer diaries

Participants consenting to wear an accelerometer were asked to complete an accompanying diary. Five accelerometer diaries were returned. As numbers were so

small, data from the diaries were keyed directly into an SPSS database at NatCen. Accelerometers were sent to UCL for processing.

Processing of outputs from measurement equipment

All outputs from the measurement equipment (such as plusoptiX, digital photographs, focimeter readings, BIA machine) have been serialised. Outputs have been reconciled against the questionnaire dataset.

Non-electronic data collection

Due to time limitations during questionnaire and SOP development, some data items were collected by paper and scanned at NatCen. Interviewers were asked to serialise each paper document with a barcode label. Data collected by paper included:

- Child observations scoring sheet (M6 and M12)
- Consent form (M28, P28, M6, M12 where electronic consent not obtained)
- Focimeter readings (M28, P28, B12)
- Eye tracking record sheet (B6, B12)

The following data was collected on paper and keyed into the questionnaire at the clinic by Reception interviewer (or the Anthropometry interviewer if urine was collected from the infant at this station).

- Urine collection sheet (B6, B12).
- Saliva collection sheet (B6, B12)

21.5 Timings data

A collaborative approach was taken to ensure that relevant and useful timings data could be collected. During the questionnaire development stage, two independent data outputs for timings data were proposed. Both form part of the data outputs for the Pilot.

21.5.1 Timestamps for pre-specified groups of questions

- In order to look at timings for modules and groups of questions within a module, it was recommended that timestamps were specified within the template module specifications for groups of questions that were of particular interest.
  - Timestamp calculations stamp the time of response at a variable and are triggered by key suppression. They must be linked to a variable that requires interviewer or participant response (i.e. not derived or computed variables that do not require key suppression).
- Where specified, timestamp variables were built into the questionnaire program. 730 timestamps were programmed.
- The output for the specified timestamps is a set of timestamp variables, which will be delivered within the final questionnaire dataset.
- Time is calculated as minutes past midnight. The calculated interval between timestamp variables allows for analysis of length of predetermined groups of questions.

- It was recommended by NatCen that timestamps were not used at each question to analyse question length as this is best analysed using the audit trail data relating to timings (see section 21.5.2).

21.5.2 Audit trail data relating to timings

- This is the output of the raw data that is taken from the audit trail. It contains the length in seconds of the intervals between each question.
- Timings are computed by suppression of key at each question.
- It is delivered separately to the questionnaire dataset and is independent of the specified timestamps that were programmed (see section 21.5.1).
- Timings are provided at participant level i.e. for each variable, individual participant timings are listed.
- The user can identify required variables and observe individual response length and calculate overall mean and spread for each question.
- The user can also use the serial number, which contains sweep and person type identifiers, to:
  - filter the questions by sweep if you are interested in whether a question response time is longer or quicker at a certain sweep
  - filter the questions by respondent type, e.g. if interested in seeing whether a question took longer on average to answer for mothers or partners

21.6 Data security

NatCen are registered (now termed 'notification') under the Data Protection Act 1998, and comply with all its obligations. In addition, NatCen is fully accredited to ISO 27001, the international standard which covers information security. To comply with this, our information security procedures are subject to regular external audit to ensure continued compliance.

NatCen assures its respondents that all information obtained will be used only for statistical or research purposes. Furthermore, no statistics or findings will be released in a way that is likely to identify an individual, unless specifically agreed with them.

Participant identifiable data has been removed from the final data outputs in order to protect the anonymity of participants.

21.6.1 Data security risks

Storage of participant identifiable data on removable storage device

A data security risk was identified relating to participant identifiable data stored on removable storage devices.

- USB sticks containing plusoptiX video data
- SD cards containing digital photographs of participant eyes, child observation video data.

In order to comply with data security regulations, Blancco File Shredder software was installed on the Reception laptop. Once data had been copied to the server from the removable storage devices it was securely wiped from the storage device. The storage device was then designated as ready to be used. A major risk implication is the loss of data. It was essential that this process was completed with accuracy and care to minimise this risk.

22 Clinic data collection

This section describes the data collection for each station/room covered by the pilot. At each station interviewers were provided with a crib sheet summarising the tasks to be conducted.

22.1 Reception

22.1.1 Summary of tasks

The reception role involved participant interaction, data collection and administrative tasks. The key tasks involved at the reception station involved:

- Welcoming participant to clinic on arrival
- Setting up of reception area and participant kitchen
- Administering short questionnaire on participant arrival and exit
  - Verification of participant using barcode on appointment letter (if available)
  - Arrival questionnaire covering whether participants had brought items listed on appointment letter
  - Exit questionnaire, including checking of contact details and availability for post-clinic feedback interview
- Issuing cash envelopes containing £11 towards travel expenses to participants (and up to one accompanying adult)
- Downloading of data from Vision and Child Observations stations
  - Vision: digital photographs from SD card, Plusoptix video data from USB
  - Child observations: video data from SD card
- Filing and organising participant paperwork, including 'Risks and Issues' log which was held on Reception
- Keying of urine and saliva collection sheets (M6 and M12 only)

22.1.2 Timings

Timings for booking in are outlined in the table below. A change in protocol meant consents were administered in the CAPI station for the Pilot, as so booking in did not include the consent process.

Table 22.1 Reception booking in timings (minutes)			
	Mean	**Min**	**Max**
M28 (n = 26)	2	1	6
P28 (n = 6)	1	1	2
M6 (n = 4)	2	2	3*
M12 (n = 5)	2	1	2
All (n = 41)	3	1	39

* A maximum time of 39 minutes was recorded, but this outlier has been removed as it is due to recording error

22.1.3 Equipment

- Laptops (one for Reception tasks and one for keying of saliva sheets)
- Barcode reader
- SD card reader for data download
- Wireless printer for printing of consent forms
- Secure box, where secure documents and monies were locked when required

22.1.4 Issues arising in Pilot study

- As Reception was the first and last station to be visited, it required prompt and organised set up and shut down.
- There were no locked storage facilities available at Reception. As there were monies and participant details being stored at reception, it was essential that it was covered by a Life Study staff member at all times.
- The intention was that USB sticks and SD cards would be reused throughout the Pilot, so video data was required to be downloaded from the SD card during the clinic session. Each video needed to be downloaded, renamed and then securely deleted from the SD card in order to adhere to data security guidelines. Due to the size of the video files and technical issues with server connection, it was recommended by IT that the data was not downloaded during live participant data collection. Each video file takes around the length of the recording to copy and securely delete from the SD card. This is a time-consuming process and would not have been possible to manage were the clinic at full capacity, even accounting for connectivity issues.
- As USB sticks and SD cards were being reused during the data collection period, a system was established to ensure that 'data for download' and 'SD cards/USB sticks ready for use' were stored separately to minimise risk of data loss.

22.2 CAPI and consent

22.2.1 Summary of tasks

CAPI was the first clinic station that the participant visited. Tasks for the CAPI interviewer involved:

- Verification of participant
- Administering electronic consents using a Windows 8 tablet
- Carrying out a face to face interview, which collected information from participants on topics such as
  - Demographics
  - Pregnancy and birth
  - Parental employment
  - Financial situation
  - Childcare
  - Child health
  - Infections and immunity

22.2.2 Timings

The table below shows the mean time spent at the CAPI station. This ranged from 21 to 30 minutes, with partners having he shortest average interview and mothers with babies (6 and 12 months) the longest.

Table 22.2 CAPI and consent timings (minutes)

	Mean	Min	Max
M28 (n = 26)	24	16	41
P28 (n = 6)	21	13	26
M6 (n = 4)	30	19	38
M12 (n = 5)	30	22	42
All (n = 41)	25	13	42

22.2.3 Administering of consents

A specification for the Pilot was to capture digitised consents. An electronic version of the consent form was developed, which allowed for capture of digitised consent form. A Windows 8 tablet was required for consents administration.

To ensure that the time taken to administer consents was obtained, interviewers were asked to enter the main CAPI questionnaire using their CAPI laptop. An interviewer instruction then prompted interviewers to administer consents using the consent tablet.

Interviewers explained to participants how to complete the form using the tablet. Interviewers then checked and countersigned the consents, saved the form and then sent it to print. The printed copy was brought to the CAPI room and placed in the participant folder. An electronic pdf and CSV file of the consent form was saved on the tablet (which was backed up to the server at the end of the clinic session).

During the clinic period, there were technical issues which resulted in some consent forms being collected on paper. These were photocopied to ensure that the participant had a copy of their signed form and NatCen retained the original. In total, 31 electronic consent forms and 10 paper consent forms were collected.

All participants consented to all statements in the consent forms although during the telephone feedback interviews, some participants reflected that they would have liked more information on 'regulatory authorities' and information on how data would be linked to medical records. See section 20.6 for further detail.

22.2.4 Equipment

- Laptop
- Barcode reader
- Windows 8 tablet with stylus
- Showcards

22.2.5 Issues arising in Pilot study

- Technical issues with consent tablets resulted in ten paper consents being obtained instead of electronic format.
- Smaller numbers meant that the clinic supervisor was able to hand deliver consent form from the printer but may not be possible with higher volumes of participants.
- Feedback on the questionnaire suggested that the questions about fertility history should be asked with sensitivity

22.3 CASI

22.3.1 Summary of tasks

The CASI station entailed the participant completing a self-completion questionnaire using a computer with a touch screen monitor during the clinic visit.

- During CAI development UCL specified that the CASI interview should be split into two sections, CASI 1 and CASI 2, due to the length of the questionnaire. Participants therefore typically visited the CASI station twice during their visit.
- Between two and four CASI stations were set up each day depending on expected number of participants.
- Interviewers were responsible for logging the participant into the CASI questionnaire and verification.
- A hard-wired keyboard was available for participants if they required as there were a number of open questions within the questionnaire.

- Once interviewers had demonstrated the CASI questionnaire using example questions their role was to monitor the CASI station and log participants out when they had completed their questionnaire.
- CASI content covered a wide range of topics, which included:
  - Pregnancy and birth
  - Parental mental health
  - Parental behaviour and lifestyle
  - Environment
  - Neighbourhood
  - Parental education

22.3.2 Timings

Timings for CASI 1 and CASI 2 are outlined below. Mothers with 12 month old babies had the shortest time on CASI (35 minutes on average across CASI 1 and 2). The other participants had similar times (ranging from 48 minutes on average for M28 to 51 minutes for P28).

Table 22.3 CASI timings (minutes)

	Mean	Min	Max
CASI 1			
M28 (n = 26)	20	9	28
P28 (n = 6)	27	16	44
M6 (n = 3)	24	15	37
M12 (n = 5)	17	12	20
All (n = 40)	21	9	44
CASI 2			
M28 (n = 24)	28	19	41
P28 (n = 5)	24	12	29
M6 (n = 3)	26	18	39
M12 (n = 5)	18	12	28
All (n = 37)	26	12	41

22.3.3 Equipment

- Windows 8 machine with touch screen monitor
- Barcode reader
- Mouse and keyboard

22.3.4 Issues arising in Pilot Study

- Location of CASI stations for the Pilot were not ideal as the stations were spread across two separate areas, making it difficult for interviewers to monitor and be on hand for participants when at full capacity.
- Length of CASI was reported by participants directly and interviewer feedback. Some participants reported that they were not thorough in their responses towards the end.
- It was observed and reported during feedback that where parents attended with babies or young children, the infants would often either sleep or become agitated during CASI due to the length of the questionnaire. This had implications for measurements at other stations. Participants asked to wait while their baby slept before visiting the next station or the infant would arrive at the next station feeling agitated and it could be difficult to take the measure.
- Key CASI questions flagged as problematic included
  - Cosmetics questions; not enough space for all cosmetics used for some participants, 'face' is not a response option, which was overwhelmingly raised by participants as a query both during live data collection and post-clinic feedback.
  - Five most visited locations; many people did not know full address, time consuming to answer.
- Some interviewers and participants felt that the size of the screens meant that privacy was compromised. Others felt that the environment itself was too open.
- Full participant feedback on the CASI station can be found in section 20.6.

22.4 Measurements

Table 13.1 summarises measurements covered during pilot data collection for each participant type. This section outlines the tasks required at each measurement station and highlights key issues encountered during data collection.

Detailed protocols and equipment lists for all measurements can be found in individual SOPs and are available from the Life Study Team.

22.5 Adult anthropometry

22.5.1 Summary of tasks

A range of anthropometric (physical) measurements were carried out by interviewers. M28, P28 and M12 participants were eligible to visit the Anthropometry station. Adult anthropometric measurements collected depended on participant type. Measures included:

- Weight
- Bioelectrical Impedance Analysis (BIA)
- Height
- Sitting height

- Waist circumference
- Triceps and subscapular skinfold thickness
- Mid upper arm circumference (MUAC)
- Fitting of accelerometer and placement of accelerometer diary (M12 only)
  - Participants were provided with return packaging addressed to NatCen.

To ensure quality control, all measurements taken by interviewers were repeated two or three times, except the BIA measurement which was only attempted once.

Results of measurements obtained by interviewers were recorded in CAPI. Data from the BIA machine was wirelessly transmitted to the seca laptop.

22.5.2 Timings

Table 22.4 outlines overall timings for Adult Anthropometry. On average Adult Anthropometry took around 20 to 25 minutes across all the participant groups. However, there was a lot of variability, which will need to be considered when planning flows for the main stage if similar measurements are taken.

Table 22.4 Adult anthropometry timings (minutes)

	Mean	Min	Max
M28 (n = 26)	25	16	38
P28 (n = 6)	20	18	25
M12 (n = 5)	23	14	40
All (n = 37)	24	14	40

22.5.3 Equipment

- Laptop (for general data collection)
- Laptop (for seca data only)
- Barcode reader
- seca 862 scales (weight)
- seca 274 stadiometer (height)
- seca mBCA 515 (BIA machine)
- Stool/bench and footrest and metal retractable measuring tape (sitting height)
- Easy Check tape measures (waist circumference)
- seca 212 tape measures (MUAC)
- Holtain skinfold Caliper (skinfold thickness)

Milton wipes were also available to ensure hygiene.

22.5.4 Issues arising in Pilot Study

- Technical issues were encountered with connectivity between the seca 274 stadiometer and the seca BIA machine, which were caused by daily manoeuvring of the stadiometer, affecting calibration and wireless functionality. This was resolved by securing an alternative room to use for Anthropometry, which provided a stable storage solution for the stadiometer and BIA machine.
- The cooler temperature in the anthropometry room sometimes caused participant discomfort when removing clothes to enable measurements to be carried out. A BIA reading could not be obtained from one participant as they had very cold hands and feet, which meant that they could not be detected by the BIA machine and analysis could not take place.
- On occasion, BIA readings were attempted but not successfully obtained for M28 participants. It was speculated that this could perhaps be due to foetal movement affecting the stability of the scales. Further investigation recommended for main stage.
- Where the expectation was to use a fixed clinic flow, the longer than anticipated timings for Anthropometry sometimes resulted in bottlenecks. See section 19.3 for detail on clinic flow.
- All five M12 participants wore an accelerometer and completed an accelerometer diary for seven days following their clinic visit. Telephone reminders were carried out and all accelerometers and diaries have been returned by participants to NatCen. Accelerometers were sent to UCL for data download.
- Participants who attended the clinic with young children commented that infants could become fractious without dedicated adult attention and sometimes disrupted the measurements e.g. one infant removed the lead from the BIA machine, another held onto the side of the machine during the measurement.
- Participants would have appreciated prior notification that they would be expected to undress for the measurements, enabling them to wear appropriate clothing. Some participants expressed unease at having to remove clothing for skinfold thickness measurements. See section 19 for detailed participant feedback.

22.6 Infant anthropometry

22.6.1 Summary of tasks

Trained NatCen nurses carried out anthropometric measurements with B6 and B12 participants. M12 measurements were completed first and B12 immediately afterwards.

- Infant weight
- Infant head circumference
- Infant mid upper arm circumference (MUAC)
- Infant length
- Triceps and subscapular skinfold thickness
- Urine collection

- Urine collection kit administered following CAPI interview. Urine collection was usually administered at Anthropometry. Otherwise urine sample obtained outside of Anthropometry and collection tube handed to Reception.

To ensure quality control, all measurements taken by interviewers were repeated two or three times.

Results of measurements obtained by nurses were recorded in CAPI.

22.6.2 Timings

Timings for infant anthropometry are outlined below. In all cases where infant urine was collected, this was done as part of the anthropometry. Urine was not collected for three infants. We have provided timings for both scenarios

.

Table 22.5 Infant anthropometry timings (mins)

Anthropometry plus urine timings			
	Mean	**Min**	**Max**
B6 (n = 2)	22	21	23
B12 (n = 4)	23	15	30
All (n – 6)	22	15	30
Urine collection timings			
	Mean	**Min**	**Max**
B6 (n = 2)	1	1	1
B12 (n = 4)	3	1	4
All (n – 6)	2	1	4
Anthropometry only			
	Mean	**Min**	**Max**
B6 (n = 2)	21	20	21
B12 (n = 1)	24	24	24
All (n = 3)	22	20	24

22.6.3 Equipment

- Laptop
- Barcode reader
- seca 376 scales (weight)
- seca 416 Infantometer (length)
- seca 212 tape measures (MUAC and head circumference)

- Holtain Skinfold Caliper (skinfold thickness)

Milton wipes were also available to ensure hygiene.

22.6.4 Issues arising in Pilot Study

- Due to flow of measurements, B6 and B12 infants sometimes spent a significant length of time undressed. A recommendation to consider for the main stage would be to reorder the measurements to minimise the length of time the baby has to be undressed.
- Infants often became fractious and upset while anthropometric measurements were taken. Where Infant Anthropometry took place towards the end of the clinic visit, observations and feedback highlighted that babies had often just woken from a sleep and it could take a while to settle them.

22.7 Vision assessments (adult and infant)

22.7.1 Summary of tasks

At the Vision station, interviewers carried out a range of vision assessments with M28, P28 and B12 participants. All participants attending the Vision station were eligible for the following assessments:

- Plusoptix assessment
- Frisby (stereovision) test
- Short interviewer administered CAPI questionnaire focusing on vision issues

The following assessments were not necessary for all participants. Interviewers were provided with a laminated flow chart to determine which measures were required. The CAPI programme also instructed interviewers as to which protocol to follow. Full details can be found in SOPs.

- Digital photo (M28s & P28s eligibility depended on Plusoptix reading; all M12s eligible)
- Focimeter reading (if glasses worn and available)
- Transcription of glasses prescription (if available)

22.7.2 Timings

The timings for Vision are summarised below. Participants spent 16 minutes on average at the Vision station. This included a short CAPI interview as well as the measurements. This measurement also had a wide range of times (from 6 minutes to 34 minutes).

Table 22.6 Vision timings (minutes)			
	Mean	**Min**	**Max**
M28 (n = 25)	16	6	34
P28 (n = 6)	17	7	32
B12 (n = 4)	16	10	25
All (n = 35)	16	6	34

22.7.3 Equipment

- Laptop
- Barcode reader
- Plusoptix S09 Vision Screener including monitor
- USB stick (connected to Plusoptix S09 Vision Screener)
- Frisby plates x 3
- Digital camera and battery
- SD card (one per clinic session for digital camera)
- Focimeter including printer

22.7.4 Issues arising in Pilot Study

- Considerable IT development was required in order to enable the Plusoptix Vision Screener to interface with Blaise and enable data to be transferred to the laptop.
- Data outputs from the Plusoptix Vision Screener were captured as follows
  - pdf and txt files saved directly to laptop connected to Plusoptix Vision Screener
  - Video data saved to USB that needed to be inserted into back of device. Separate USB sticks were required for each participant and needed to be removed following Plusoptix measurement. The USB was then placed into a serialised envelope and handed to Reception for download.
- Digital photographs were stored on an SD card and manually uploaded to the network at Reception. One USB card was used to store photographs throughout each clinic session and could contain photographs of multiple participants. A photograph of the barcode label was taken immediately before the photograph of participant eyes to allow for individual serialisation of data during download.
- Given the complexities involved in data capture from the Plusoptix Vision Screener, some issues were encountered with saving of Plusoptix data during data collection.
  - On occasion interviewers did not follow correct protocol and the USB stick was not inserted into the Plusoptix device. Therefore video data was not captured for these participants.

  - Set up and pack down of equipment each day had implications on saving data outputs. On one occasion the Ethernet cable connecting the laptop and Plusoptix device was not connected, which resulted in missing data.
  - Poor WiFi connectivity at the CRF affected the application designed to transfer data from the Plusoptix to the laptop. The system froze and interviewers could not proceed with remainder of vision assessments. Additional Blaise programming resolved some of the issues and allowed interviewers to recall Plusoptix if the WiFi signal dropped, which enabled a retake of the Plusoptix assessment and continuation with vision assessments.

- Interviewers were inexperienced in conducting vision assessments and did not have an ophthalmological background. There was lots of new and complex technology to become familiar with which proved a challenge and it was difficult for interviewers to gain the experience required for administering vision assessments, though they managed to overcome the difficulties and collect data from most participants.
  - There was limited time for group interviewer training at the CRF with all equipment available
  - WiFi connectivity issues during early training at the CRF meant that sometimes interviewers lacked confidence in the technology
  - Small participant numbers paired with intermittent shift patterns meant it was difficult for interviewers to develop and maintain their skills.
  - Inexperience with using the equipment added to the time taken at the vision station.

- Interviewers reported issues when administering the Frisby test with 12-month participants as they were not always engaged in the test e.g. some infants were teething and were more interested in chewing the plate. Interviewers would have benefited from training and guidance from experts experienced in collecting vision assessments in young infants.
- Eligibility for a digital photograph of the eyes among M28s and P28s depended on readings from Plusoptix Vision Screener. Interviewers were required to refer to flow diagrams in the SOP. Some interviewers found the flow diagrams and tables confusing and often took photographs ‘just in case’. The SOP also detailed uniocular testing, which was not conducted in the Pilot.
- If participants wore bifocal or single vision glasses and had brought them to the clinic, the focimeter was used to determine and print the prescription of the glasses. Participants who had brought a copy of their prescription as requested in the appointment letter questioned the purpose of bringing the prescription when a measurement of their lenses was taken in the clinic.
- A short interviewer administered CAPI questionnaire collected information on participants’ and families’ vision.
  - It was felt that some of the response options in this section required interviewers to have a working knowledge of ophthalmology.
  - Participants sometimes queried the definition of ‘immediate family’ and were unsure who to include.
  - Laser eye surgery was not accounted for within the questionnaire.

22.8 Eye Tracking / GAP task

22.8.1 Summary of tasks

All infant participants were eligible for the GAP task. Two interviewers were required to administer the test.

- On arrival at the Eye Tracking station, the mother was asked some initial questions by the interviewer to ensure eligibility (must have sight in both eyes) and the measure was explained in more detail.
- The interviewer positioned the mother and infant in front of the Tobii Eye Tracker and instructed the interviewer controlling the script to start playing a short cartoon to distract the infant.
- Calibration was carried out. Once complete, interviewers manually checked calibration points against a sheet of laminated examples to determine whether calibration was of good quality.
- On completion of calibration, the GAP task commenced. This consisted of a series of sequences and stimuli being displayed on the Eye Tracker. Interviewers needed to attract the infant's attention to the screen if the infant looked away.
    - The script took approximately five to seven minutes to run depending on how quickly the baby moved their gaze.

22.8.2 Timings

Timings for eye tracking are outlined below.

Table 22.7 Eye tracking timings (minutes)

	Mean	Min	Max
B6 (n = 3)	15	12	19
B12 (n = 4)	16	13	22*
All (n = 8)	16	12	22

* One B12 child eye tracking was timed at 51 minutes. This outlier has been removed from the calculations.

22.8.3 Equipment

- Laptop
- Apple MacBook to run the MatLab scripts
- Barcode scanner
- Tobii T120 Eye Tracker
- Hydraulic height-adjustable arm
- Webcam and Webcam laptop (to view the participant from behind the curtain)
- Dell monitor (to view the video clips as viewed by the participant)
- Stereo speakers, sub woofer and sound meter

- Curtain
- Pinhole glasses (worn by mothers to ensure only the infants' eyes were being tracked)

Figure 22:1 Eye-tracking data collection equipment (administrator's view)

22.8.4 Issues arising in Pilot Study

- The GAP task was considered to be straightforward and easily administered by interviewers.
- The use of laminated calibration plots aided calibration interpretation.
- Interviewers struggled with setting up of the station.
  - Involved complex IT set up at the start of each weekend shift.
  - Only set up over weekends meaning limited scope for interviewers to fully learn and understand set up procedures and equipment.
- Interviewers were required to screw the Tobii Eye Tracker monitor to a hydraulic arm. This was a time consuming process and involved risks around safety of expensive and delicate equipment.
- A key task for Eye tracking was to position the participant in front of the Eye Tracker correctly in order for calibration to commence. Delays in receiving a working hydraulic height-adjustable arm meant it was unavailable for training days and therefore not possible to fully demonstrate the protocol to interviewers. Time for practice was limited to a short session before participant arrival at the clinic due venue restrictions. Subsequently interviewers struggled with positioning participants within the 3D track box using the hydraulic arm.

22.9 Child development observations

22.9.1 Summary of tasks

Two Child development observation stations were set up at weekends, one for 6-month participants and another for 12-month participants.

6 month Child development observations

Some of the B6 Child Development tasks involved observation of interaction between the mother and infant. The observations carried out (requiring the use of two video cameras) were:

- Restraint in car seat
- Mother's still face
- Maternal infant interaction.

Interviewers had a number of tasks to carry out prior to, during and following the measurement. These included:

- Entering CAPI data to ensure timings were collected
- Positioning of video cameras
- Filming barcode label (to enable serialisation of data at download)
- Explanation of observations to the mother and administration of task
- Positioning of participants
- Coding and scoring of observations

12 month Child development observations

The observations for B12s were child-focussed and involved interviewer coding and the use of one video camera to record:

- Restraint in high chair
- Joint attention task.
- In addition, a play task was administered between the observations. This was designed for interviewers to build up rapport with the infant.

As with the B6 observations, interviewers were required to carry out a number of tasks prior to, during and following the measurement. See above for further details.

22.9.2 Timings

The table below summarises timings for the Child development observations station.

Table 22.8 Child development observation timings (minutes)

	Mean	Min	Max
B6 (n = 3)	28	21	34
B12 (n = 5)	17	11	24

22.9.3 Equipment

- Laptop
- Barcode reader
- 3 x video cameras, tripods and batteries (two for B6 tasks and one for B12 tasks)
- SD cards
- Stop watch (Mother still face, Restraint in highchair, Maternal infant interaction, Restraint in car seat)
- Car seat (Mother still face, Restraint in car seat)
- Large cushions / bean bag (Mother still face)
- Play mat (Mother still face)
- Posters (Joint attention task)
- Highchair (Joint attention task, Restraint in highchair)
- Table and chairs (Joint attention task)
- Comfortable chair (Maternal infant interaction)
- Activity board (Maternal infant interaction)

Milton wipes and muslin cloths were available to ensure hygiene and cleanliness.

22.9.4 Issues arising in Pilot Study

- Interviewers sometimes lacked confidence in administering the observations as there was limited opportunity to practise measures using 'real' infants.
- Interviewers were carrying out multiple tasks throughout the observations, including operation of video cameras, directing participants, operating CAPI and coding of measurements. This carries with it a risk that data was not collected, scoring was rushed or timings become inflated. Streamlining of the number of tasks required to be conducted by a single interviewer would be beneficial.
- The room used for B6 observations within the CRF was not considered suitable for child participants.
  - There was insufficient room to manoeuvre around the cameras and tripods
  - The clinical nature of the venue meant it could be hazardous for young children, containing open sharps boxes, trays of needles and other clinical consumables, lots of other equipment on display with exposed cables and wires
- Participants commented that it was hard to act natural with their baby knowing that they were being filmed. Interviewers and participants sometimes found the 'Mother's still face' exercise difficult when the infant became distressed. See section 19.4 for participant feedback.
- The play task implemented part way through B12 observations intended to build rapport was felt to add additional complication to the task. Babies became engaged in the toy and were disappointed when it was taken away from them. It was agreed that play task could be removed from the protocol during the final week of data collection.

- Parents frequently expressed concerns or sought reassurance following the 'Joint attention' task if their baby did not look at or point at any of the posters. Posters were not considered to be age appropriate by M12 participants.

22.10 Infant biosamples: urine

22.10.1 Summary of tasks

Infant urine samples were collected from six of the nine infant participants (two M6s and four M12s). Details of all procedures can be found in the biosamples SOPs.

22.10.2 Processing of urine samples

As no process had been set up for urine processing, samples collected in the pilot were discarded in clinical waste bins at the CRF. NatCen flagged this as a missed opportunity and suggested that it would be advisable to also test procedures for courier and analysis of urine samples in preparation for the main study.

22.10.3 Summary of timings

In the pilot, urine collection occurred as part of the infant anthropometry assessment and the overall station time includes time to administer the collection. The timings for separate urine collection are shown in Section 22.6.2. On average, urine collection took around 2 minutes.

22.10.4 Equipment for urine samples

- 3 (medium sized) cotton wool balls
- 20 ml syringe
- Disposable Nitrile gloves
- Screw top specimen container for urine sample
- Sealable plastic specimen bag
- 15cm Ruler (to record height of liquid in specimen tube)

22.10.5 Data collection and issues arising in the Pilot Study

Urine samples were collected by the NatCen nurse (usually during the infant anthropometry measurements). The protocol was for mothers to place the cotton-wool balls in the barrel of the syringe and administer the collection themselves.

- None of the mothers completed the urine collection themselves. The preference was for the urine samples to be collected by the nurse.
- Minimal amounts of urine were collected. Of the six infants who provided a sample a mean of 1.43 cm of urine was measured in specimen tubes. In certain instances a urine sample was attempted but the infant had not passed any urine by the time they arrived at infant anthropometry.
- Participants noted that the cotton wool balls moved around in the nappy and therefore didn't absorb as much urine as would have been possible.

- The SOP instructed participants or the nurse to transfer saturated cotton wool balls into syringes wearing gloves then transfer the specimen tube into a clear plastic bag and seal the bags wearing the same gloves. This was flagged as a contamination risk to UCL during training sessions. NatCen suggested the use of tweezers for this element to avoid contamination as well as facilitate the insertion of cotton wool balls into the syringe barrel.
- During post clinic telephone interviews participants seemed happy for their child to provide a sample however they were unclear as to the purpose of the collection. One participant also commented that because she had not realised the length of the clinic visit she had not brought enough nappies for her child for the duration. Parents are asked to remove their child's nappy for the urine collection so the provision of enough nappies is essential.
- Not providing specimen tubes with volume markings did not allow for testing of the equipment to be used for the main stage. As no samples were processed more rigorous testing will be necessary for the main stage.

22.11 Infant biosamples: saliva

22.11.1 Summary of tasks

Infant saliva samples were collected from six of the nine infant participants (three M6s and three M12s). Saliva samples were collected by the Clinic Supervisor (trained nurse). Eligibility, consent, timings and any problems experienced with the saliva sample were recorded on a 'Saliva Collection Sheet' by the Clinic Supervisor and entered into CAPI at Reception. Details of all procedures can be found in the biosamples SOPs.

22.11.2 Processing of saliva samples

Once the saliva sample was completed, specimen tubes were stored in the server room at the CRF and collected by a member of the CRF staff to store in the on-site laboratory.

22.11.3 Summary of timings

Timings for saliva sampling are outlined below.

Table 22.9 Saliva (minutes)

	Mean	Min	Max
M6	7	5	9
M12	7	5	8

22.11.4 Equipment for saliva samples

- Oragene DNA (OG-575) kit
- Disposable Nitrile gloves
- Scissors

- Milton wipes (to clean the scissors)

22.11.5 Data collection and issues arising in Pilot Study

Due to the length of time required for saliva sampling a separate room was required for collection.

- During post clinic follow up interviews participants commented that the saliva sample took a long time to collect even if the infant naturally produced quite a lot of saliva. Timings indicated that the procedure took on average seven minutes for both M6s and M12s.
- The saliva sample could only be taken if the infant had not eaten or drunk in the last 10 minutes. This was a factor that had to be built into participant flow. In some instances a saliva sample was not taken as the infant had fallen asleep.

23 Risks and Issues

An Issues log and Risk Register was kept throughout the pilot contract. Issues/Risks during the pilot development were noted in the monthly project board reports.

23.1 Issues during pilot development

- A meeting in early June took place to identify early risks and issues with suggestions as to how NatCen could best deliver the pilot.
- The Mac laptop supplied by UCL for the GAP task developed a fault and had to be taken by NatCen staff to be repaired under warranty.
- An additional item (focimeter) was suggested for inclusion at the start of August, leaving very little time for SOP development and understanding. The equipment had to be re-delivered as it was faulty the wrong model had been delivered.
- Delivery of the hydraulic arm for the GAP task did not arrive in working order in time for interviewers to undergo training before having to use it on pilot participants.
- Insufficient notice to get Research Passports meant early appointments had to be rescheduled or cancelled.
- Late clarification over insurance cover of equipment.
- Late confirmation that additional costs associated with the substantial variations to the Pilot would be met.
- Two breaches of information security surrounding information passed from UCL to NatCen.

23.2 Risks noted during pilot development

- Risks around not having the opportunity to review the pilot questionnaire content with regard to appropriateness of questions, ambiguity of wording/response options, loss of contextual framework etc.

- Risks around development and testing time needed re: late delivery of measurement equipment to NatCen particularly those requiring integration with other pilot data collection devices.
- Risks around testing time allowed for increased questionnaire content
- Risks around not knowing until very late on, the venue for the pilot or the operational details (number of rooms, working hours etc).
- Risks around co-ordination of SOPs development for the GAP task where the device was supplied by Acuity but the software and SOP were supplied by Birkbeck.
- Late finalisation of SOPs and arrangements for biosample processing.
- Late delivery of consumables to allow sufficient time to develop interviewer training materials.
- Risks around arrangements for safe storage of equipment and time needed to allow for this re: appointment scheduling
- Risk of hardware failure resulting from having to dismantle delicate equipment multiple times.

23.3 Issues noted during pilot data collection

An issues log was also kept at the CRF to log issues during the pilot data collection. Two issues arose:

- Metal lid from storage cage fell on an interviewer's head during close-down on 7 November.
- Fire alarm occurred on 21 November. All participants, interviewers and NatCen/UCL research staff were evacuated from the building safely. All participants completed their visit despite disruption.

The NatCen researcher on-site completed NatCen's Incident Form immediately and a copy given to UCL and to NatCen's Freelance Resources Quality Control Supervisor.

Appendix A. Data deliverables

The table below outlines the final Pilot data deliverables.

Appendix Table A:1 Life Study Pilot data deliverables

Measure	Name	Description	Respondent type	Transfer method	No. of files expected	Estimated Size	File Format
Process data	Daily dashboard report	Summary of clinic counts and timings, overall and by station.	All	Secure ftp	1 x report sent daily	c.240KB per file	Excel file
CATI	CATI process data	Containing CATI process data – data items as specified. Includes anonymised consent to contact data.	All (inc non-participants)	Secure ftp	1 x final data file	200KB	SPSS and Stata
Q're data	Interim file containing raw questionnaire data	Questionnaire, admin and timestamps data.	All	Secure ftp	1 x interim file	4,389KB	SPSS and Stata
	Questionnaire data	Questionnaire, admin and timestamps data.	All	Secure ftp	1 x final data file	5,000KB	SPSS and Stata
	Open responses	Verbatim responses to open questions (anonymised).	All	Secure ftp	1 final file	51KB	Excel
	Interviewer remarks	Interviewer remarks collected throughout data collection (anonymised).	All	Secure ftp	1 final file	30KB	Excel
Consents	Consent form data	Digitised consents not sent to UCL as participant identifiable. Consents variables can be found in questionnaire dataset.	All	Secure ftp	Delivered with final dataset	n/a	n/a
Pre-complete	Pre-complete q're data	Keyed pre-complete questionnaire data. Unedited.	M6, M12	Secure ftp	1 x per participant	c. 85KB	SPSS and Stata
	Open responses	Verbatim responses to open questions (anonymised).	M6, M12	Secure ftp	1 final file	1KB	Excel

Appendix Table A:1 Life Study Pilot data deliverables							
Post visit q're	Postal / open-ended question for M6	Single open-ended question for M6 on back of thank you letter. Letter given to participant at clinic to take home and return to NatCen in prepaid envelope. Responses scanned on receipt at NatCen.	M6	Secure ftp	1 x per participant	760KB per file	pdf
Travel payments	Signed travel payment receipts	Hard copies of signed travel payment receipts.	All	Hand-deliver to UCL	1 x per participant	n/a	Hard copy
Timings	Timings - timestamps	Specified timestamps as per q're specs. Timestamp variables can be found in the final q're dataset.	All	Secure ftp	1 final data file (processed)	n/a	n/a
	Timings - audit file	Excel files derived from the audit file containing individual timings per question per participant. 2 x files: 1 x CAPI and 1 x CASI.	All	Secure ftp	2 x files (1 x CAPI, 1 x CASI)	1,549KB	Excel
Vision	plusoptiX PDF	PDF containing photo of eyes and measurement details.	M28, P28, B12	Secure ftp	1 x PDF per participant	760KB per file	Pdf
	plusoptiX notepad file	Text data containing measurement details.	M28, P28, B12	Secure ftp	At least 1 x notepad file per participant	1KB per file	Notepad
	PlusOptix video data	Video data downloaded from PlusOptix.	M28, P28, B12	Secure ftp	1 x per participant	c. 5,500KB per file	VID
	Focimeter reading	Scanned copy of focimeter reading.	M28, P28, B12	Secure ftp	1 x per participant where required	c. 760KB per file	pdf
	Digital photograph	Digital photographs downloaded from digital camera.	M28, P28, B12	Secure ftp	At least 2 x per participant	c. 4,000KB per file	JPEG
Child observations	Video files	Child observation tasks - video clips. File name contains: serial number and camera identifier.	B6, B12	Secure ftp	1 per activity/observation	27 files ranging from 3,960KB to 863,592 KB	VLC

Appendix Table A:1 Life Study Pilot data deliverables							
	12 month observations - scoring sheet	Scanned copy of 12 month observations scoring sheet.	B12	Secure ftp	1 x per participant	c. 760KB per file	pdf
	6 month observations - scoring sheet	Scanned copy of 6 month observations scoring sheet.	B6	Secure ftp	1 x per participant	c. 760KB per file	pdf
Eye tracking	Eye tracking data	Data not part of final data delivery. MatLab data collected from eye tracking measurement is stored on the Eye tracking Mac as agreed.	B6, B12	n/a	1 x per participant	n/a	n/a
	Eye tracking behavioural record sheet	Scanned copy of infant behavioural record sheet.	B6, B12	Secure ftp	1 x per participant	c. 760KB per file	pdf
Anthropom-etry	Accelerometer diary data	Keyed data from accelerometer diary given to participants completing this measure.	M12	Secure ftp	1 x per participant	40KB	SPSS and Stata
	SECA data	SECA data collected electronically from BIA machine.	M28, P28, M12	Secure ftp	1 x per participant	74KB	CSV
Urine collection	Urine collection sheets - keyed data	Keyed data can be found in final dataset. Paper based sheets collecting administrative data for interviewer to complete if handed a urine sample by a parent at Reception (no urine collection sheet expected if completed in anthropometry).	B6, B12	Secure ftp	1 final data file (processed)	n/a	n/a
	Urine collection sheets - hard copies	Hard copy of completed urine collection sheets.	B6, B12	Hand-deliver to UCL	1 x per participant if urine collection took place outside of anthropometry	n/a	Hard copy
Saliva collection	Saliva collection sheet - keyed data	Keyed data can be found in final dataset. Paper based sheets collecting administrative data for nurse supervisor to complete during saliva collection process.	B6, B12	Secure ftp	1 final data file (processed)	n/a	n/a

Appendix Table A:1 Life Study Pilot data deliverables							
	Saliva collection sheet - hard copies	Hard copy of completed saliva collection sheets.	B6, B12	Hand-deliver to UCL	1 x per participant	n/a	Hard copy
Data security	Log files for Blancco secure deletion	Log files for Blancco secure deletions. Files saved at participant level. Not intended to form part of final data delivery.	All	Secure ftp	1 x per participant, per data type	10KB per file	HTML
Blaise files	Blaise files	Files containing Blaise code for specified questionnaire content	All	Secure ftp	n/a	1.18MB	INC File

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Appendix B: Post-visit survey for LS participants - Topic Guide

Introduction – About the research

- Introduction to researcher and NatCen – independent social policy research organisation.
- Introduction to the research: to follow-up on visit to Life Study clinic and to discuss experiences before, during and after the appointment. Get feedback on the different elements of the study, like the materials, how we communicated, the different tests and questionnaires.
- Want opinions so we can take them on board for the main project.
- [*Check whether R wants to make appointment for call-back*]
- Reminder that participation is voluntary. OK to skip questions, have right to withdraw.
- Check OK to record [NB: not intending to transcribe].
- Note that feedback provided will not be attributed to any individual in any research outputs – all anonymous.
- The interview will last around 20 minutes (no more than 30).
- Questions for researcher?

Section 1: Making contact / recruitment

Filter by recruitment path: Route A – consent to contact form
Route B – phoned / emailed TU in response to advert

Route A

Comments on:

- Initial contact with UCL: whether at antenatal clinic or other; how process worked; what liked/disliked; what appealed to R about the study; queries answered any problems?
- Consent to contact form
- Length of time between completing form and receiving call
- Initial contact with NatCen: content of CATI; queries answered; any problems?

Route B

Comments on:

- Advertisements: content and appeal – what attracted R to the study?
- Mode of initial contact: phone or email?
- Initial contact: length of time between contacts; content of CATI; queries answered any problems?

Both routes

Getting in touch subsequently - did R need to get in touch with NatCen between making first contact and the appointment?

- Ease of getting in touch (phone / email / other)
- Messages left and call-backs
- Queries made and adequacy of answers

Other pre-visit:

- Rearranging appointments
- Materials received at appropriate time
- Length of time between first contact and visit
- Whether discussed the study / whether to take part with anyone before appointment

- How to make the study more attractive / accessible to partners – suggestions for improving recruitment of fathers

Section 2: Materials

- Postcard – whether attached scan / photo? (may not have had this)
- Bookmark (may not have had this)
- PIS
- Appointment letter - whether taken to clinic? Comments on text, usefulness, timing etc.
- Pre-complete – whether completed at home / in the clinic. How long to fill in? Any problems (probe for particular questions)?

For all of the above – probe: what remembered (text / illustrations / colours / logos)? What liked / disliked?

- Anything missing in terms of materials (or would prefer in place of existing materials)? (e.g. appointment reminder card rather than letter and reminder text/email)

Section 3: Clinic appointment

- (Pros and cons of) **location**
- Adequacy of / problems with **travel expenses**
- Adequacy of / problems with **venue**
- Clinic **facilities** - any facilities really appreciated / would have liked?
- Comments on **waiting time** (probe for how long, and recommended max wait)
- Participant **packs**
- **Length** of appointment (as a whole), including:

  How long were you at the appointment?

  … hours … mins
- Comments on **flow** through clinic – liked / disliked order – preferred order?
- Specific **components** of the visit – feedback on:

  - (Pre-complete if completed at clinic)

- Reception, checking-in

- Giving consent – thoughts about process, understood this?

- CAPI

- CASI

- Anthropometry adult (and for M6 / M12 – infant anthropometry)

- Vision tests (not M6)

- (For M6 and M12) baby tests - child development, eye tracker

- (For M6 and M12) bio-samples: urine and saliva

Probe for each: time taken, whether interesting, whether (too) sensitive, given enough information before test / feedback after test, what additional information would have liked, whether any problems (i.e. child bored / needed attention)

Section 4: Post clinic

- Feelings immediately following the visit - positive and negative (enjoyment, tiredness, restlessness, embarrassment – explore for mother and baby)
- What expected from the visit? Did experience match expectations? Probe for differences between expectations and visit
- Any particular element of the visit particularly enjoyed / not enjoyed?
- Anything thought would be asked / tested and wasn't? Anything missing that should be included in clinic visit?
- Done anything differently as a result of the visit?
- Whether used of GP letter / mentioned visit to doctor
- Whether discussed visit with others
- Thank-you letter kept? Any comments on the letter / (for M6 only) whether returned additional question on back
- (If had accelerometer fitted – M12 only) experience of wearing device / any problems
- Whether would come back for another visit if invited?
- If not, why? And what (if any) changes would encourage you to repeat visit?
- Any other comments?

Thank you

If fitted with accelerometer (M12) please return device and diary

Appendix C: Interviewer feedback questionnaire

NatCen Social Research

P05011 LIFE STUDY v2

DEBRIEF QUESTIONNAIRE

Dear Interviewer

Congratulations and enormous thanks for your efforts in making the Life Study Pilot such a great achievement. It's been great working as a team and your dedication is greatly appreciated. Unfortunately we cannot have a formal face-to-face debriefing with the interviewers but we would still value your feedback and suggestions so please take your time to express your views and experiences of the Life Study Pilot.

Completing the questionnaire

The following questionnaire has been designed to capture your feedback and views on various elements of the Life Study pilot, for example the training, the facilities and the different measurements we asked you to undertake. This is so we can take on board your opinions for the pilot report. For each item please note anything you thought that was particularly good or anything you thought was particularly bad, any issues that arose or comments that you feel would be helpful to take on board for the main stage.

When you have finished answering the questionnaire, please save it in the folder on the desktop and notify the researcher.

Q1 INTERVIEWER PILOT PROFILE

Which station(s) were you briefed on?	
Which station(s) did you cover for live interviewing?	
How many shifts did you cover at CRF?	

Q2 **BRIEFINGS (Theory Day 17 Oct, on-site briefings Sun 20, Sat 26 & Sun 27 Oct)**

For this item please think about the length of the briefings, the structure of the briefings and the content.

Q2 **VENUE (CRF). For this item please think about the suitability of the venue and facilities for the tasks required for the pilot.**

Q3 **LENGTH OF APPOINTMENT AND FLOW. For this item please think about the order which participants went to various stations in the clinic and the overall length of the clinic appointment.**

Q4 **DOCUMENTS. For this item please think about the suitability of the training materials provided including protocols, daily appointment sheets etc**

Q5 **CAPI QUESTIONNAIRE. For this item please note any comments on the questionnaire content or length.**

Q6 **CASI QUESTIONNAIRE. For this item please note any comments on the questionnaire content or length.**

Q7 **STATIONS. For this item please feed back on any of the individual measurement stations e.g. Reception, anthropometry, child**

observations, vision and/or eye tracking.

Q7 **EQUIPMENT. For this item please note comments on the usability and suitability of the equipment provided for data capture.**

Q8 **COMMENTS. Please enter any other comments/suggestions you feel are relevant to the pilot report or recommendations for the main stage.**

THANK YOU FOR YOUR FEEDBACK